US006129734A

United States Patent [19]

Shturman et al.

[11] **Patent Number: 6,129,734**

[45] **Date of Patent: *Oct. 10, 2000**

[54] **ROTATIONAL ATHERECTOMY DEVICE WITH RADIALLY EXPANDABLE PRIME MOVER COUPLING**

[75] Inventors: **Leonid Shturman**, Minneapolis, Minn.; **Leonid Volkov**, Moscow, Russian Federation

[73] Assignee: **Shturman Cardiology Systems, Inc.**, Minneapolis, Minn.

[*] Notice: This patent is subject to a terminal disclaimer.

[21] Appl. No.: **08/957,942**

[22] Filed: **Oct. 27, 1997**

Related U.S. Application Data

[63] Continuation-in-part of application No. 08/792,101, Jan. 31, 1997, Pat. No. 5,779,722, which is a continuation-in-part of application No. 08/785,991, Jan. 21, 1997, Pat. No. 5,893, 857.

[51] **Int. Cl.**^{7} **A61B 17/22**

[52] **U.S. Cl.** **606/159**; 606/180; 604/22

[58] **Field of Search** 606/1, 159, 167, 606/170, 171, 184, 185, 180; 604/19, 22

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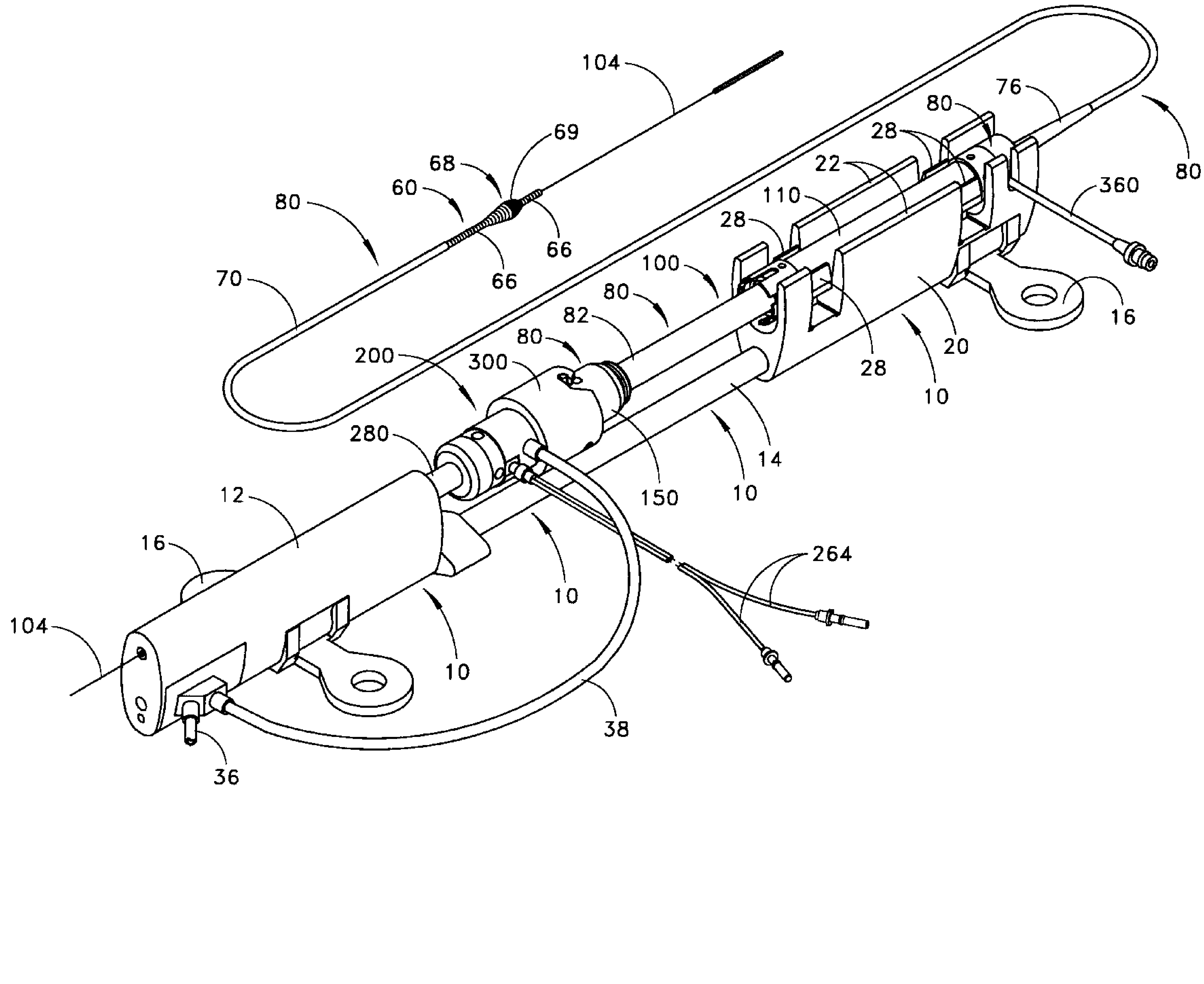
Primary Examiner—Glenn K. Dawson
Attorney, Agent, or Firm—Fredrikson & Byron, P.A.

[57] **ABSTRACT**

A rotatable atherectomy device having an exchangeable drive shaft cartridge and a rotatable prime mover coupling. The cartridge has a rotatable drive shaft socket carried by a carriage. The coupling radially expands during rotation such that it interlocks with the socket to drive a tissue removal implement on the end of a drive shaft attached to the cartridge. Upon slow or no rotation of the socket, the coupling disengages from the socket to allow for exchange of the cartridge.

157 Claims, 66 Drawing Sheets



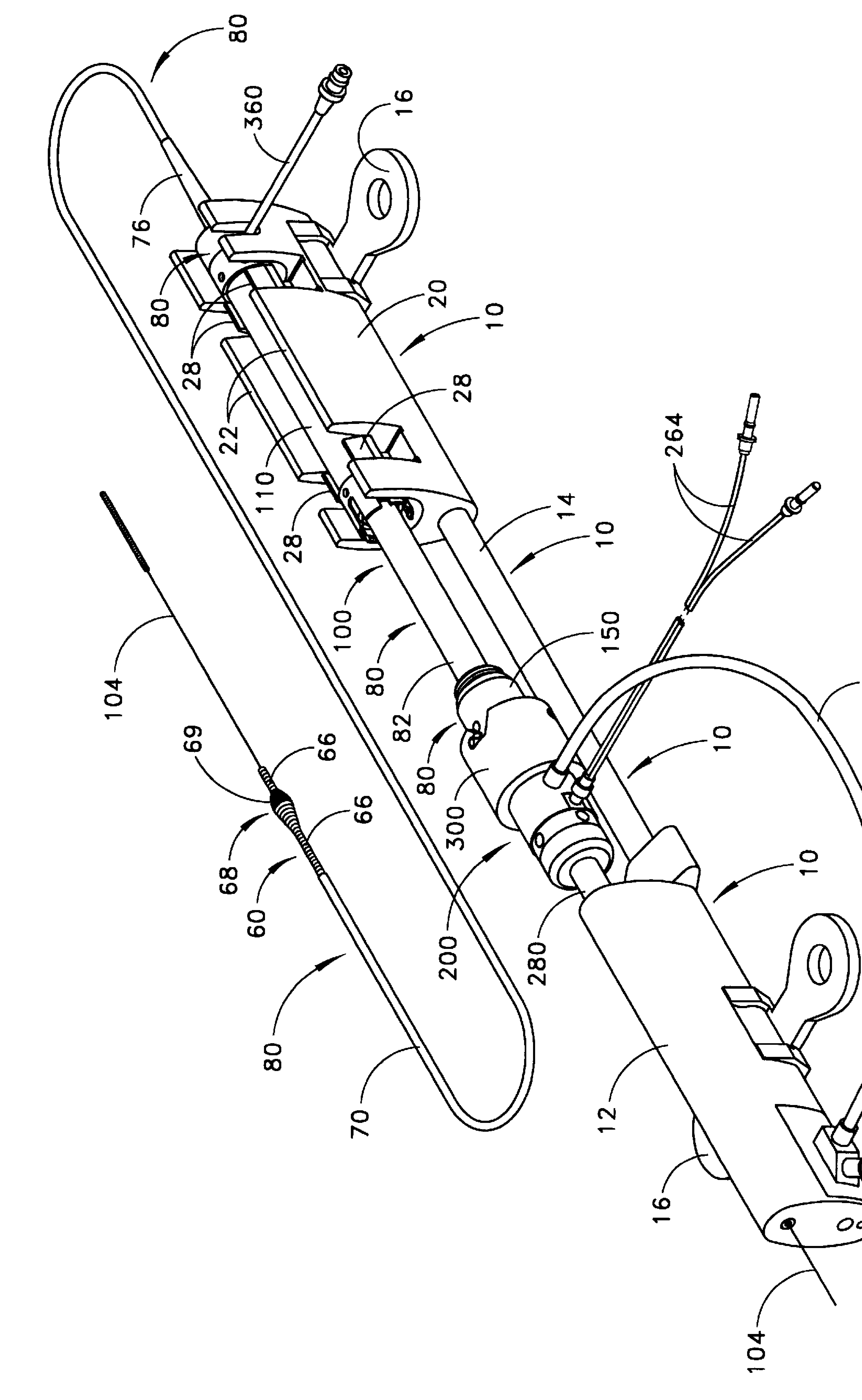

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FIG. 1

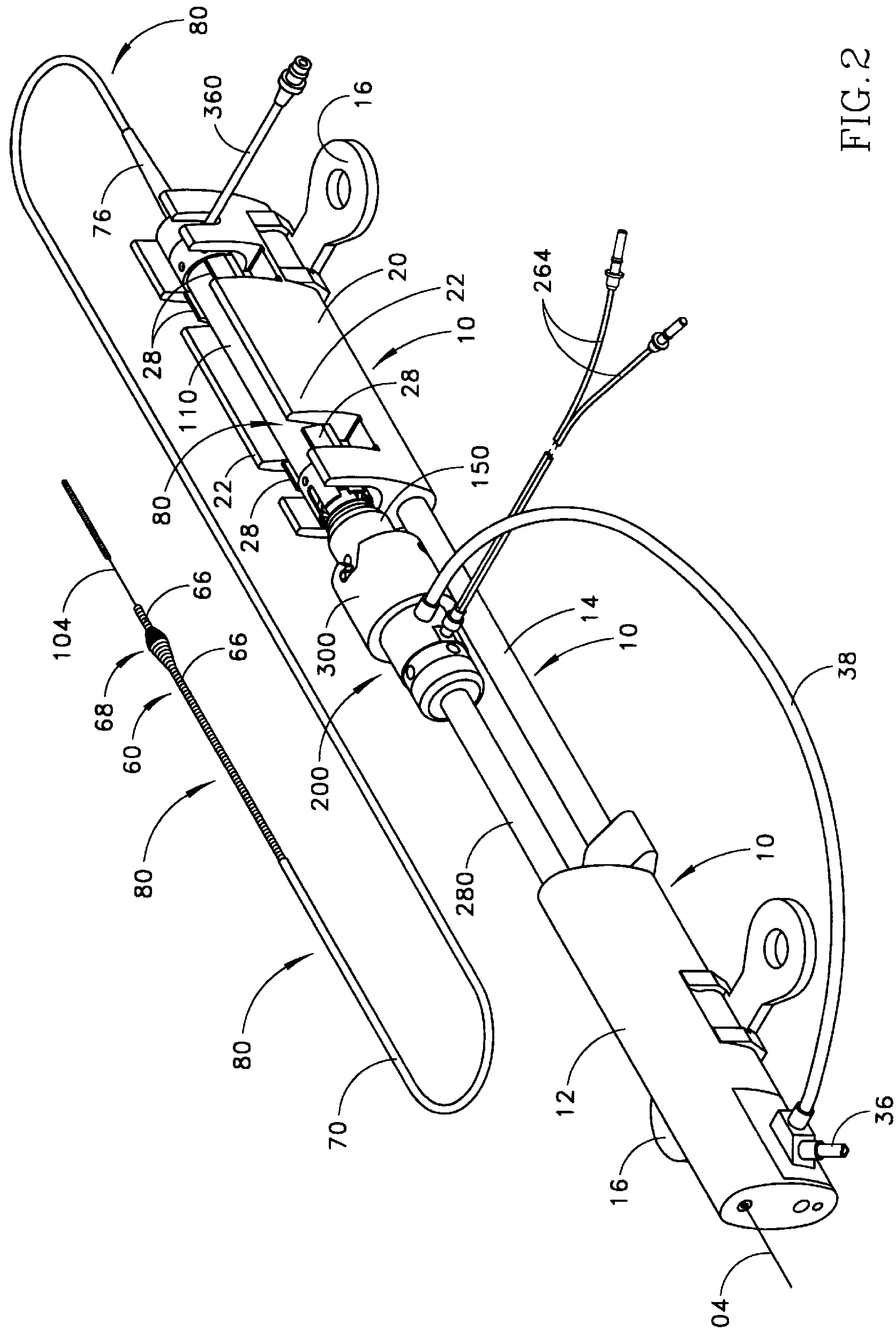
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FIG. 2

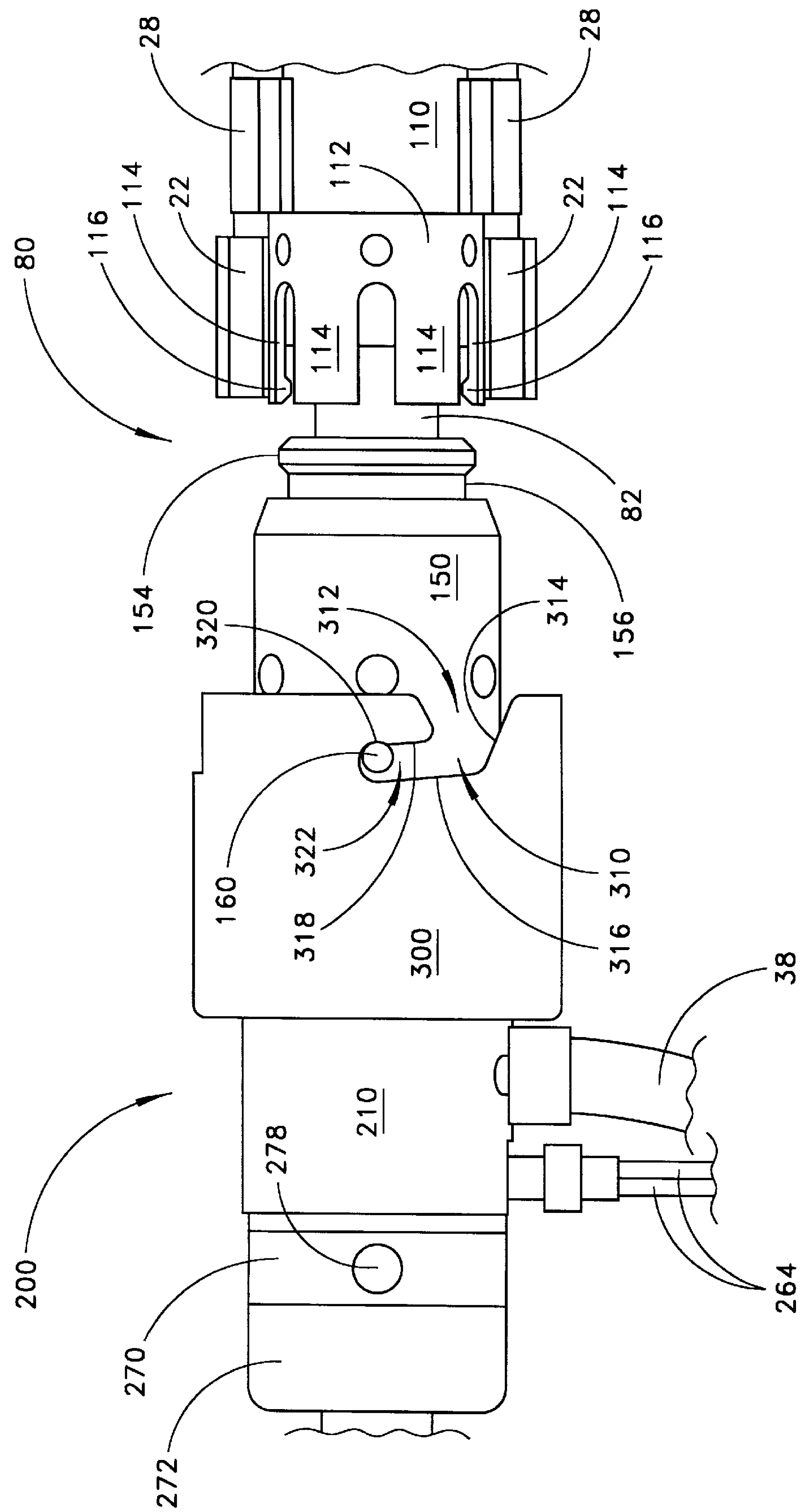
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FIG. 3

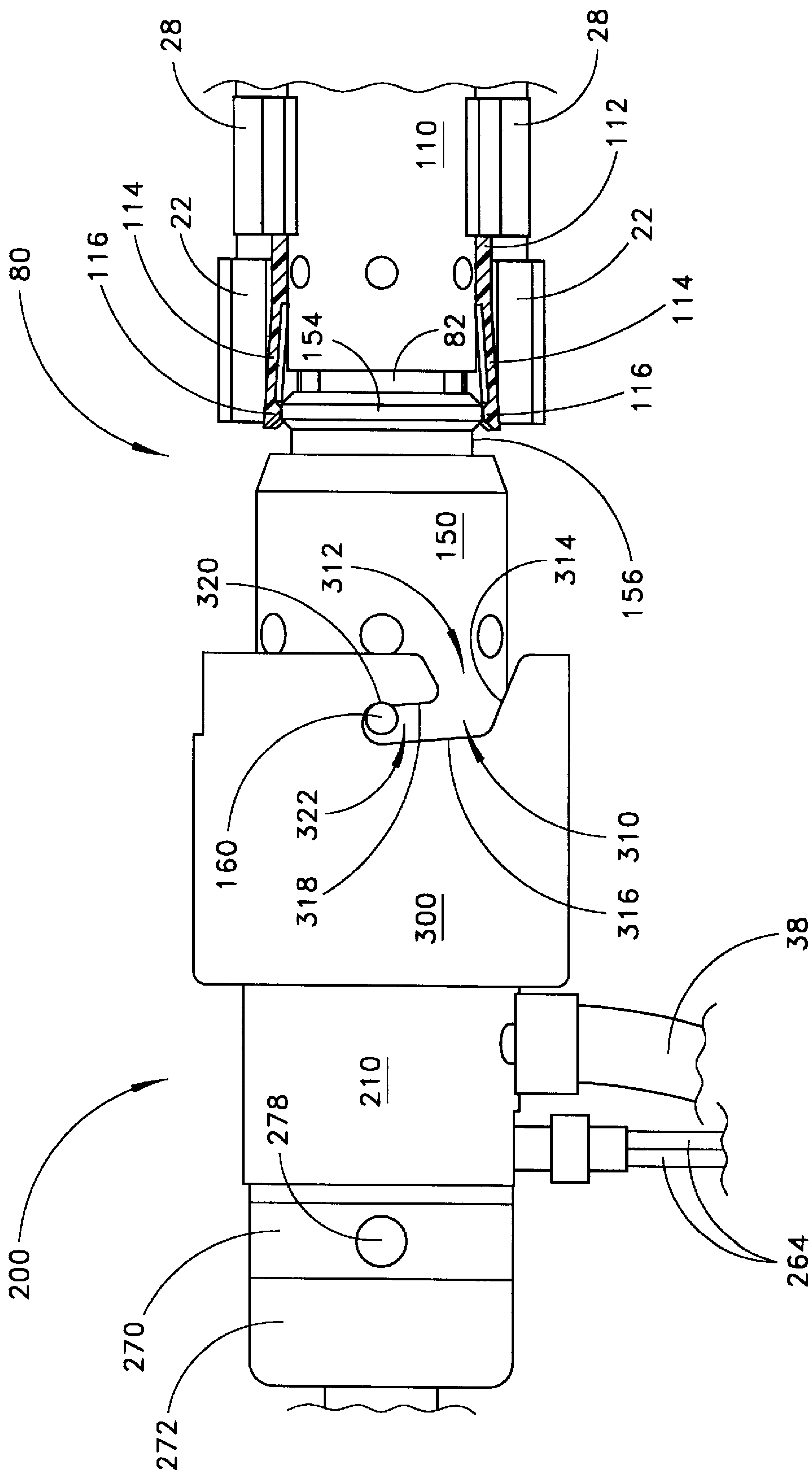
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FIG. 4

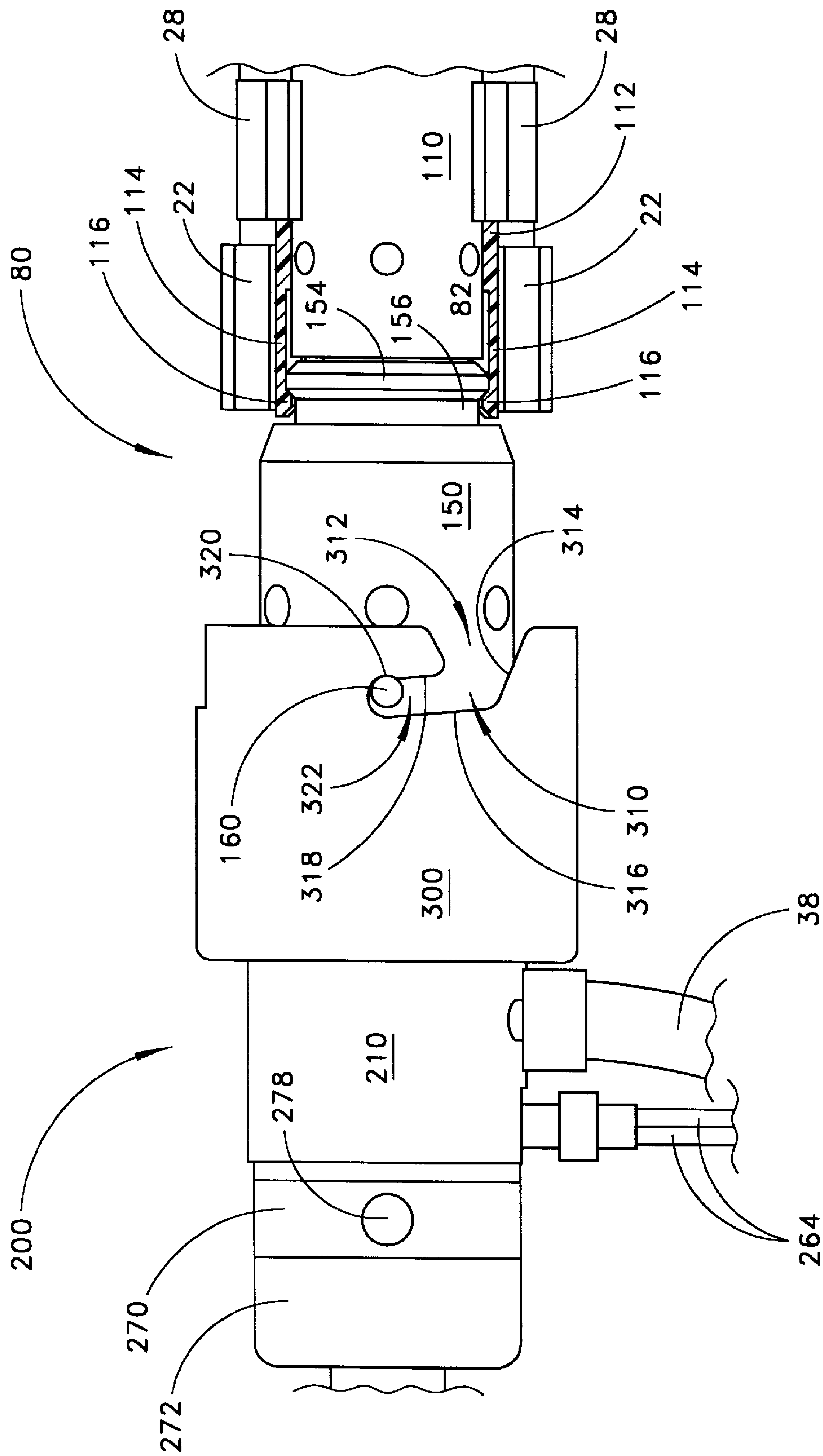
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FIG. 5

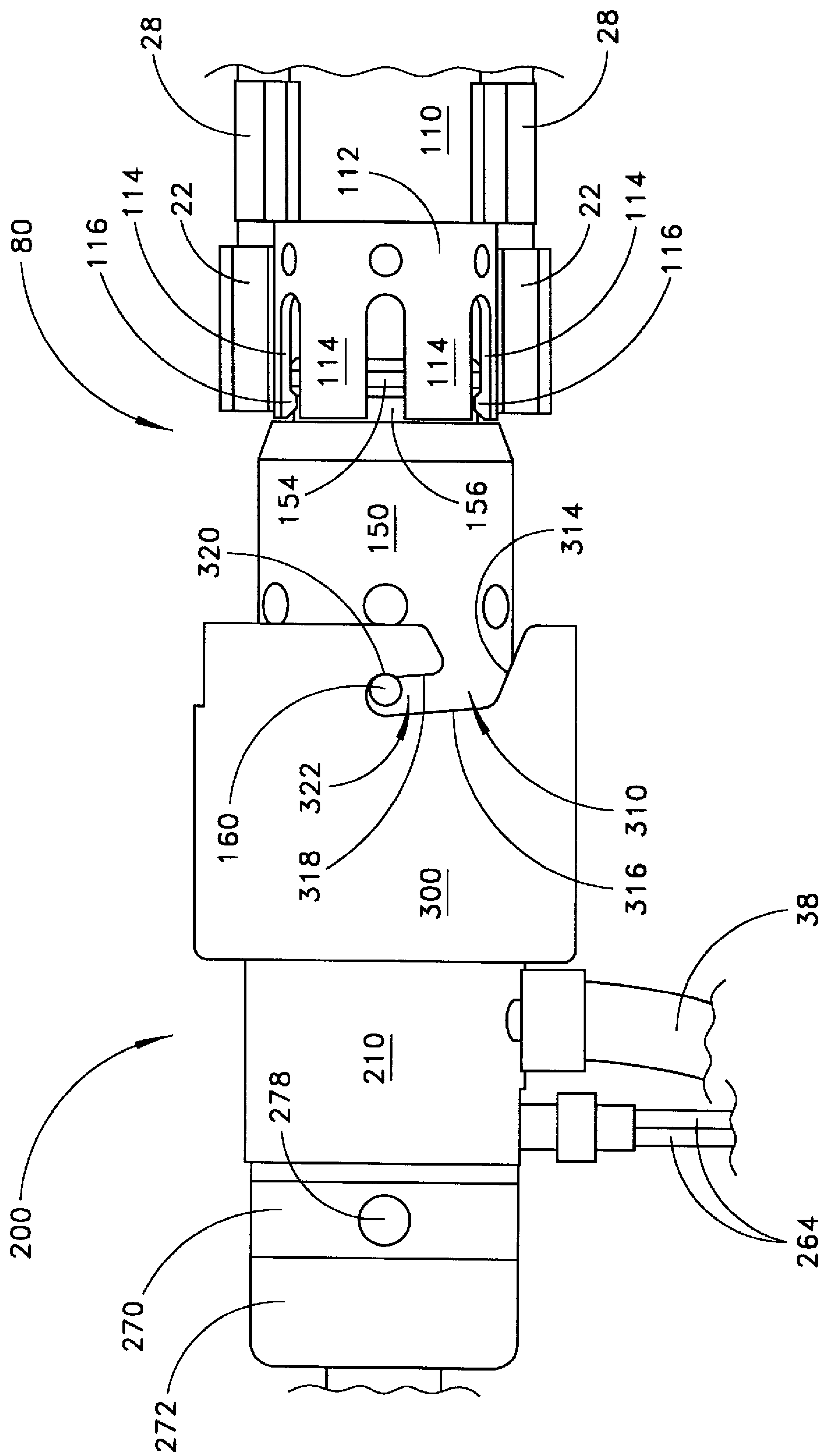
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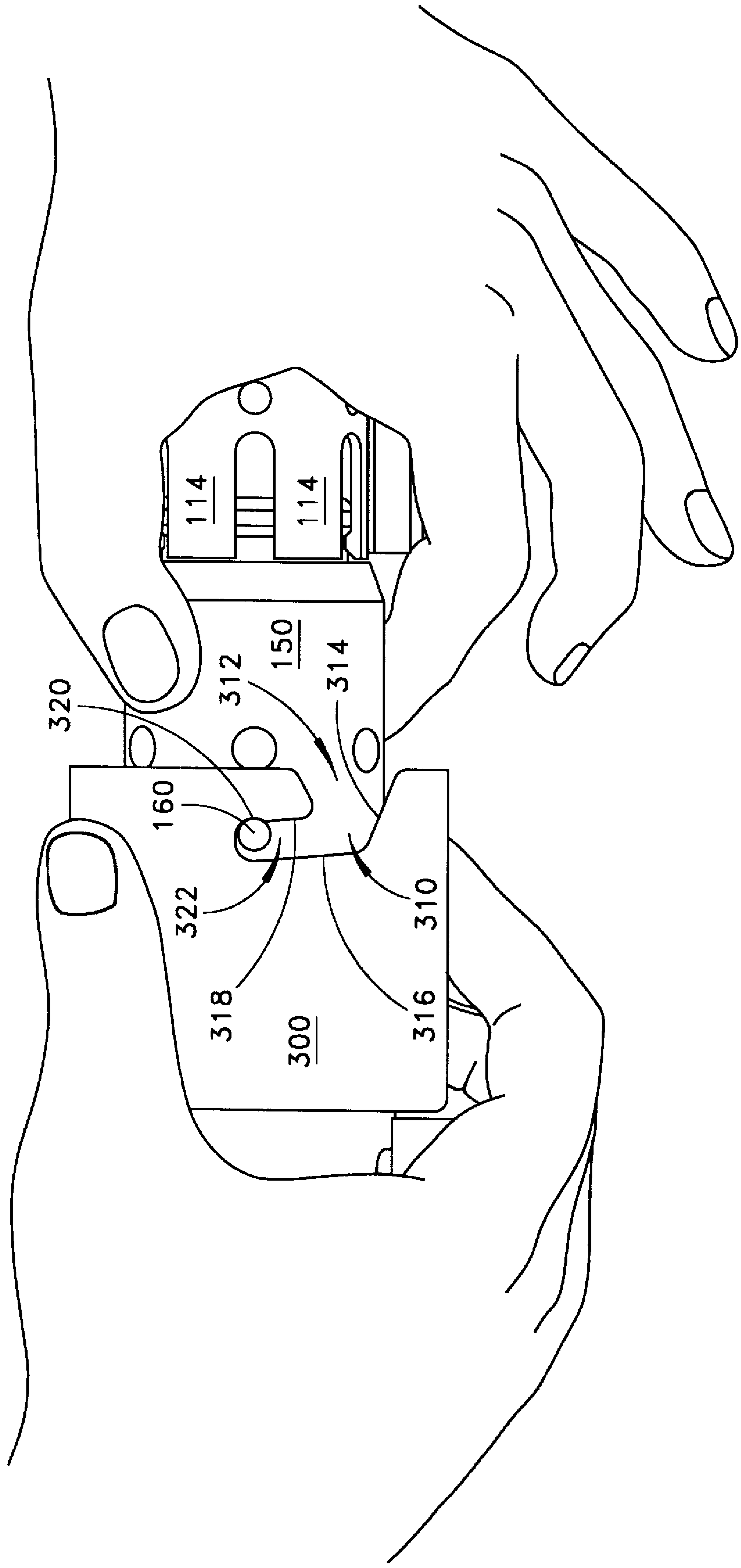
FIG. 6



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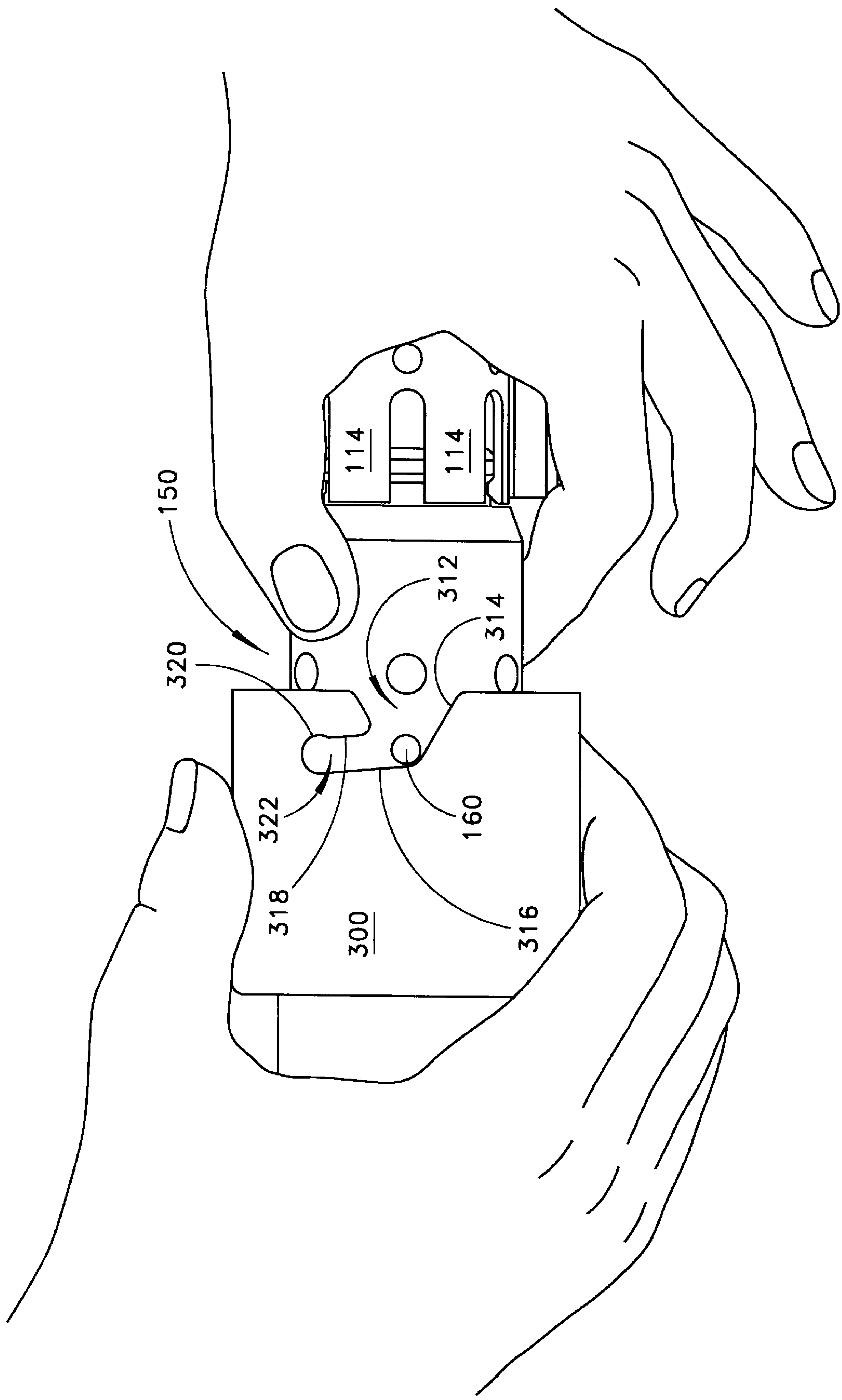

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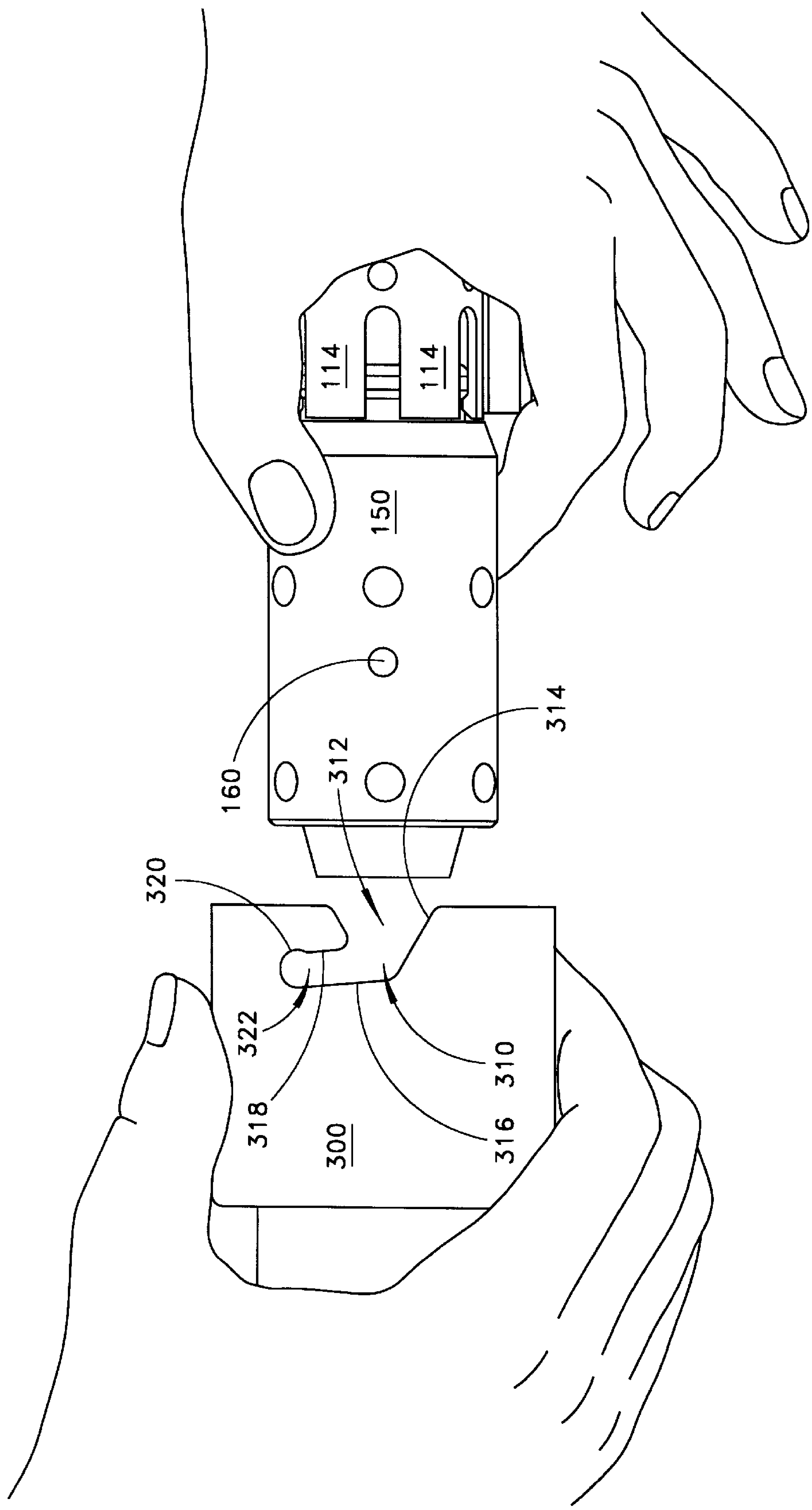

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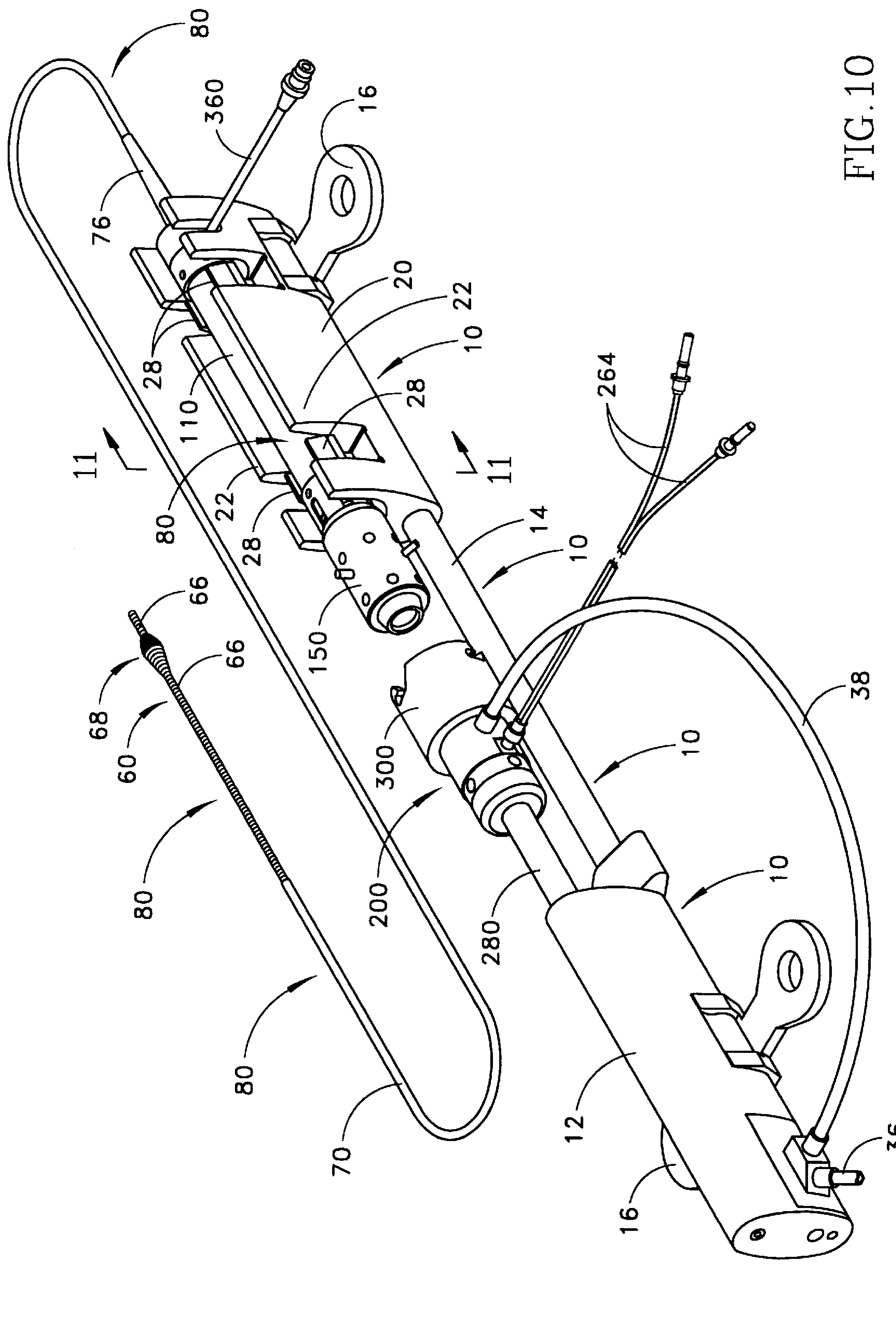
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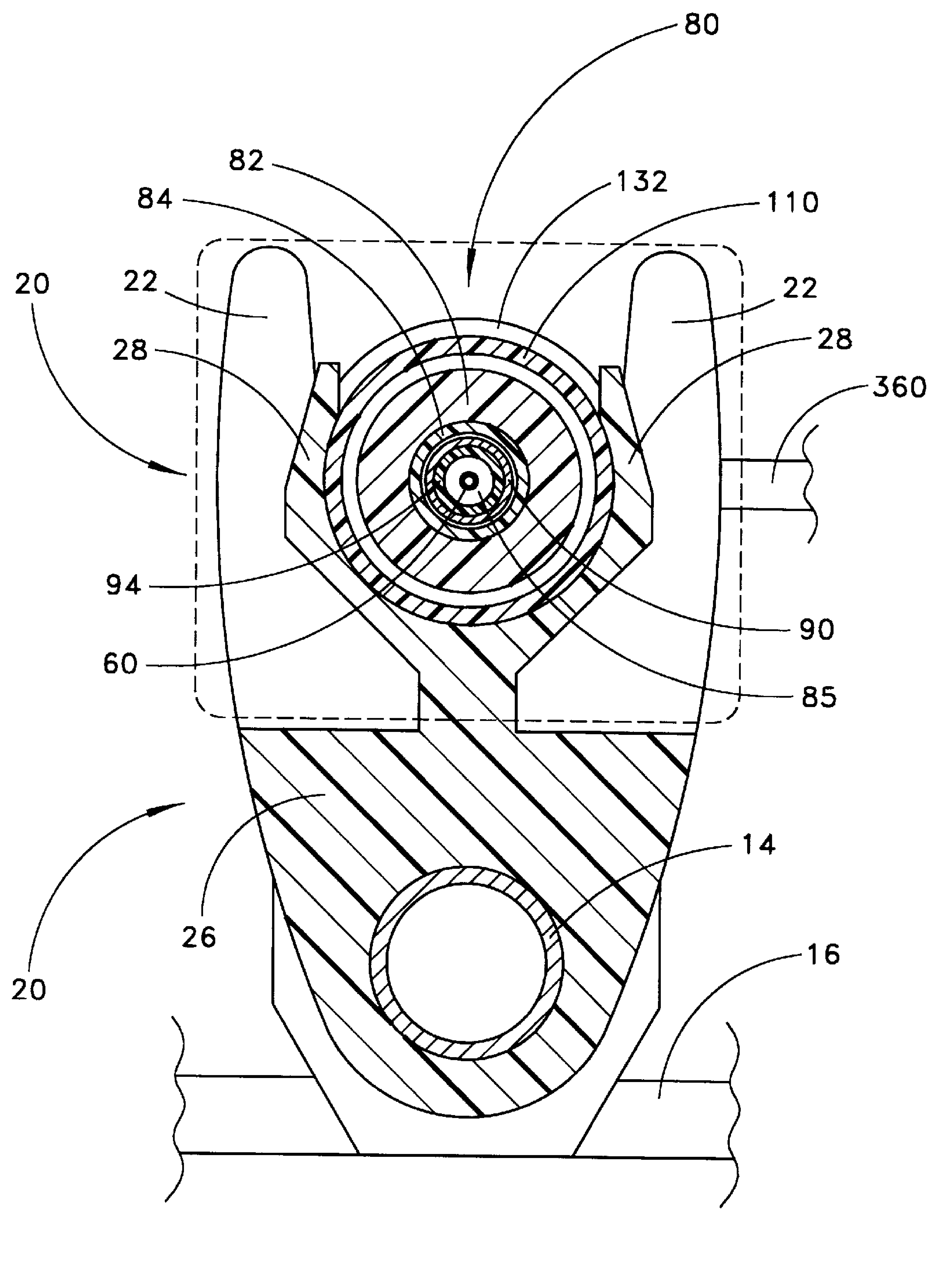
FIG.10



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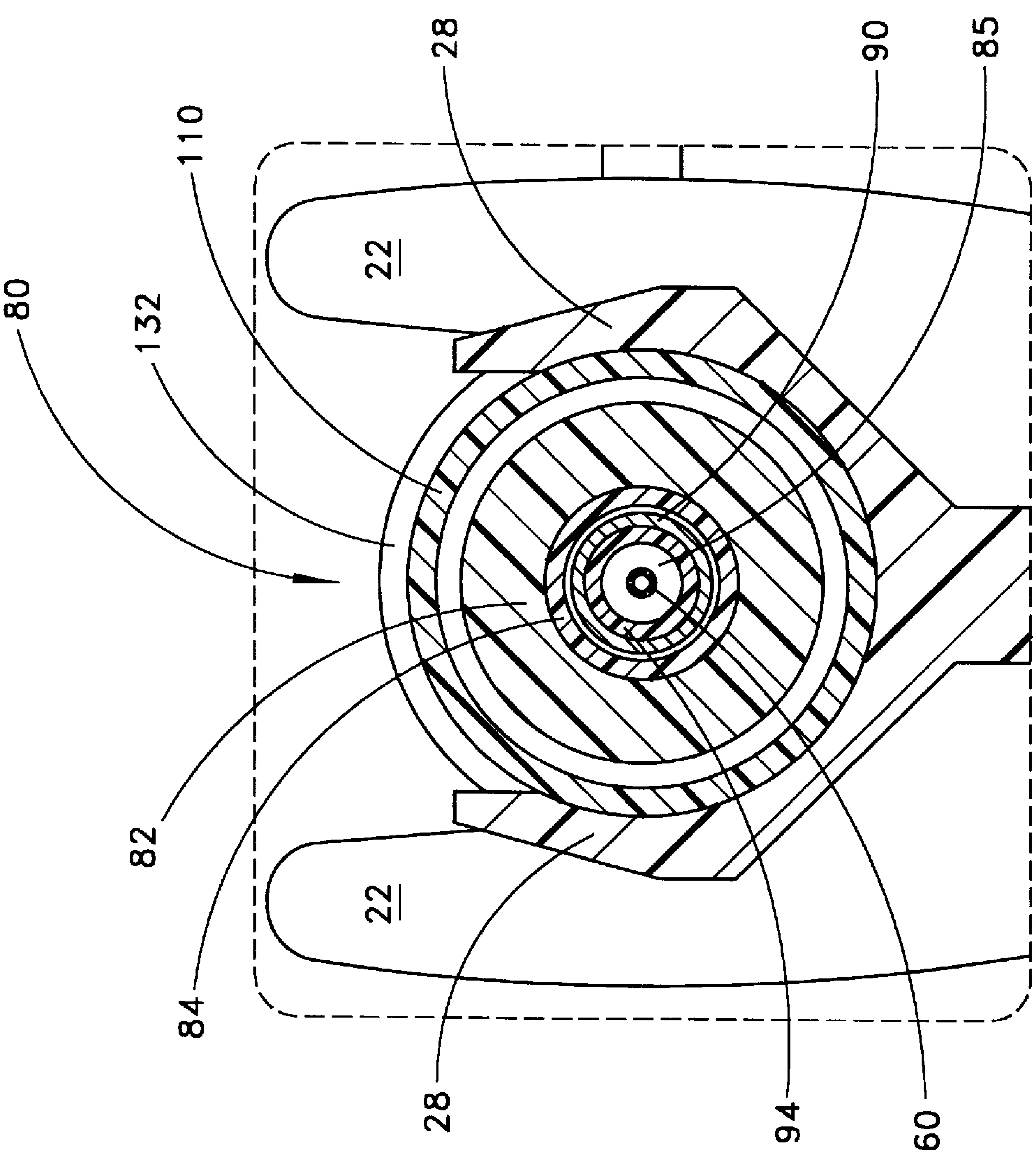

FIG.12

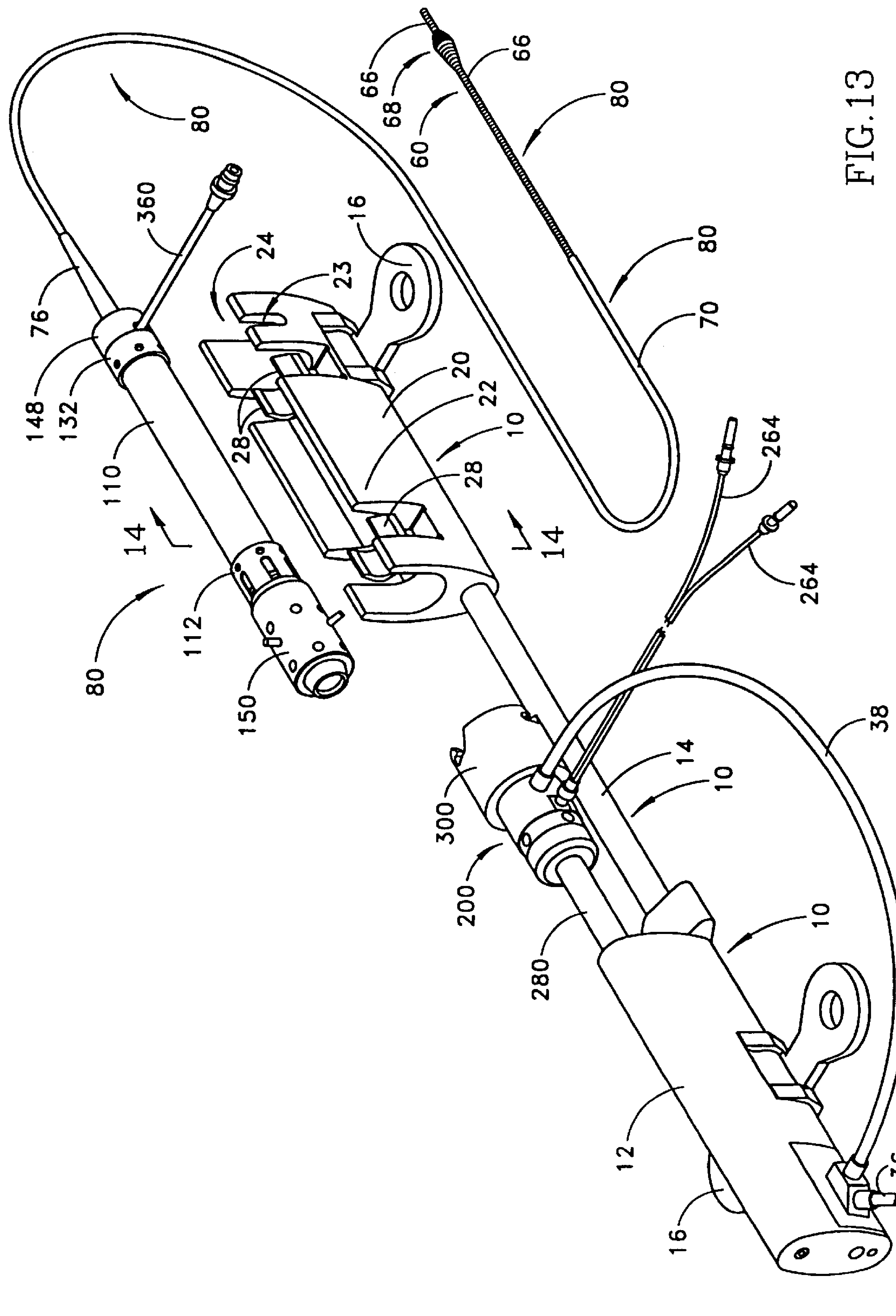
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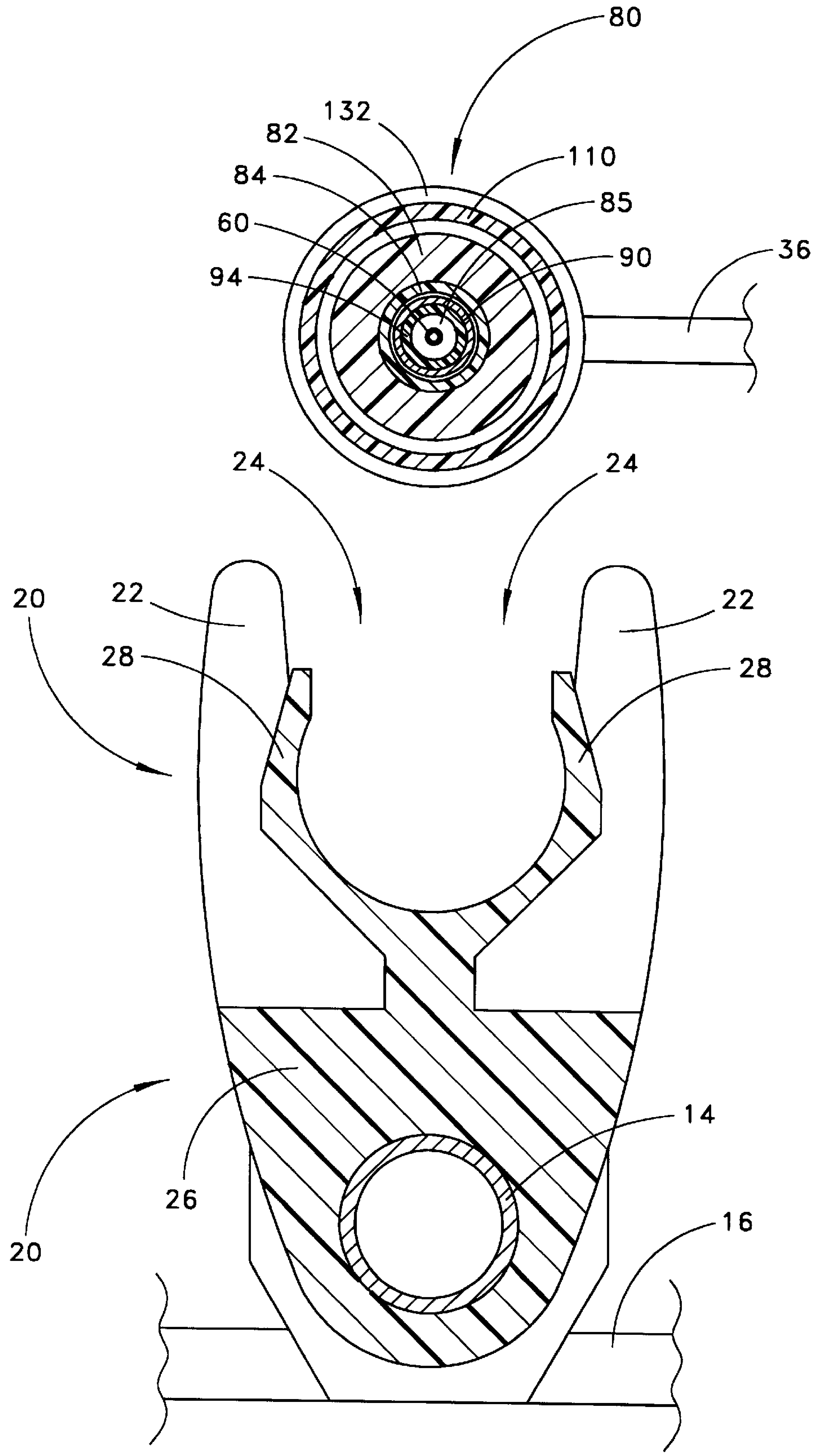
FIG.13



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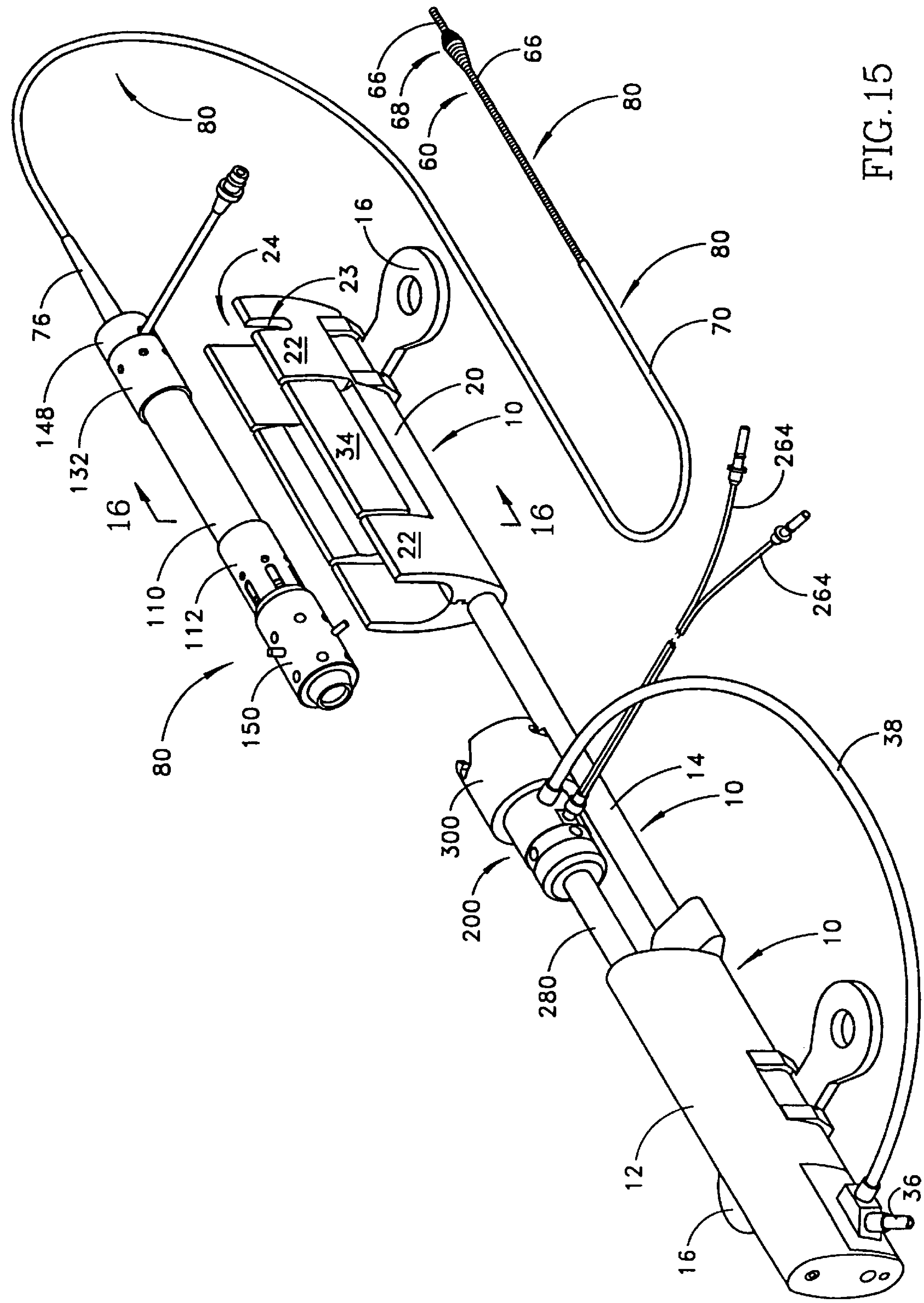
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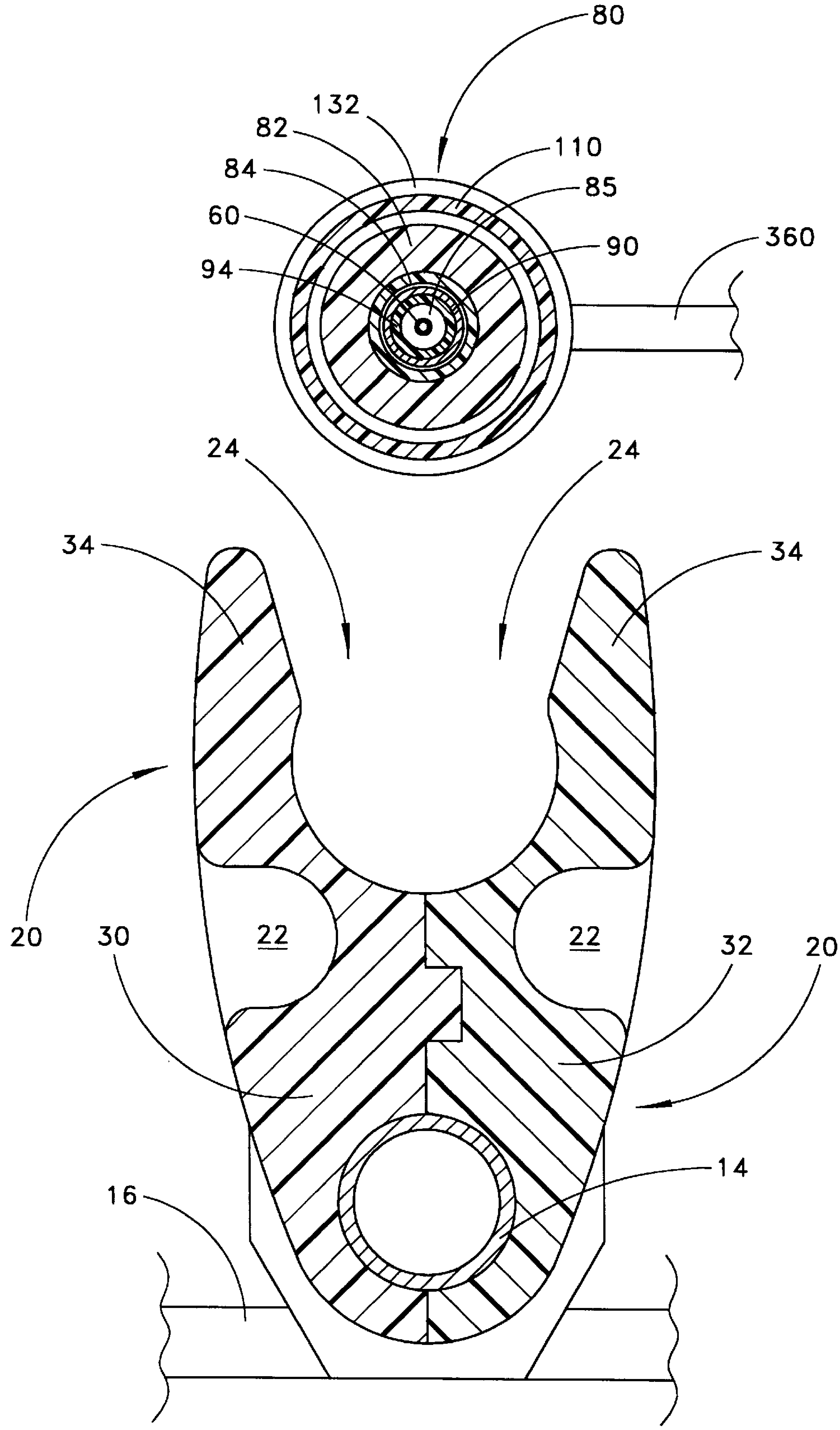
FIG. 15



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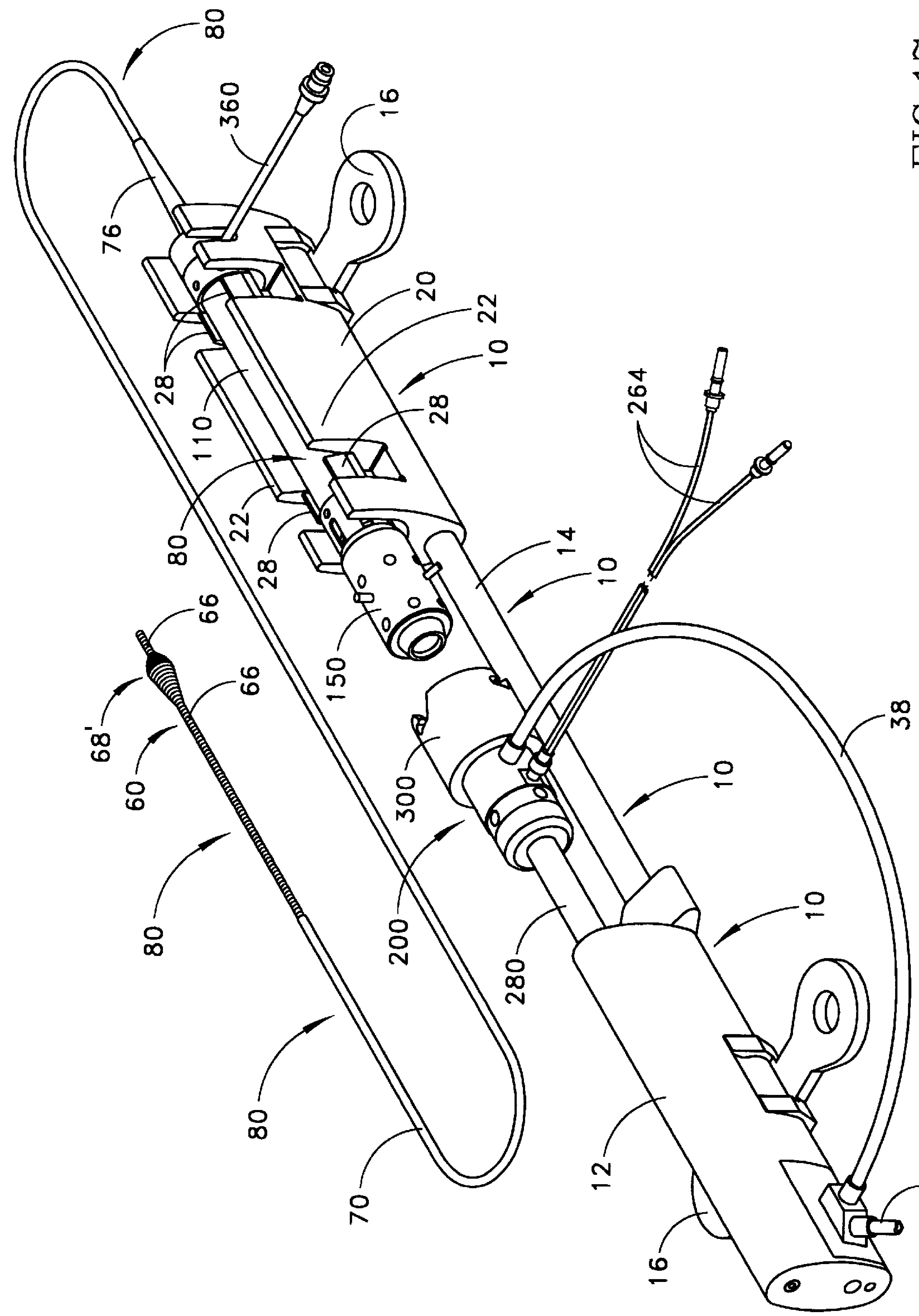
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FIG.17

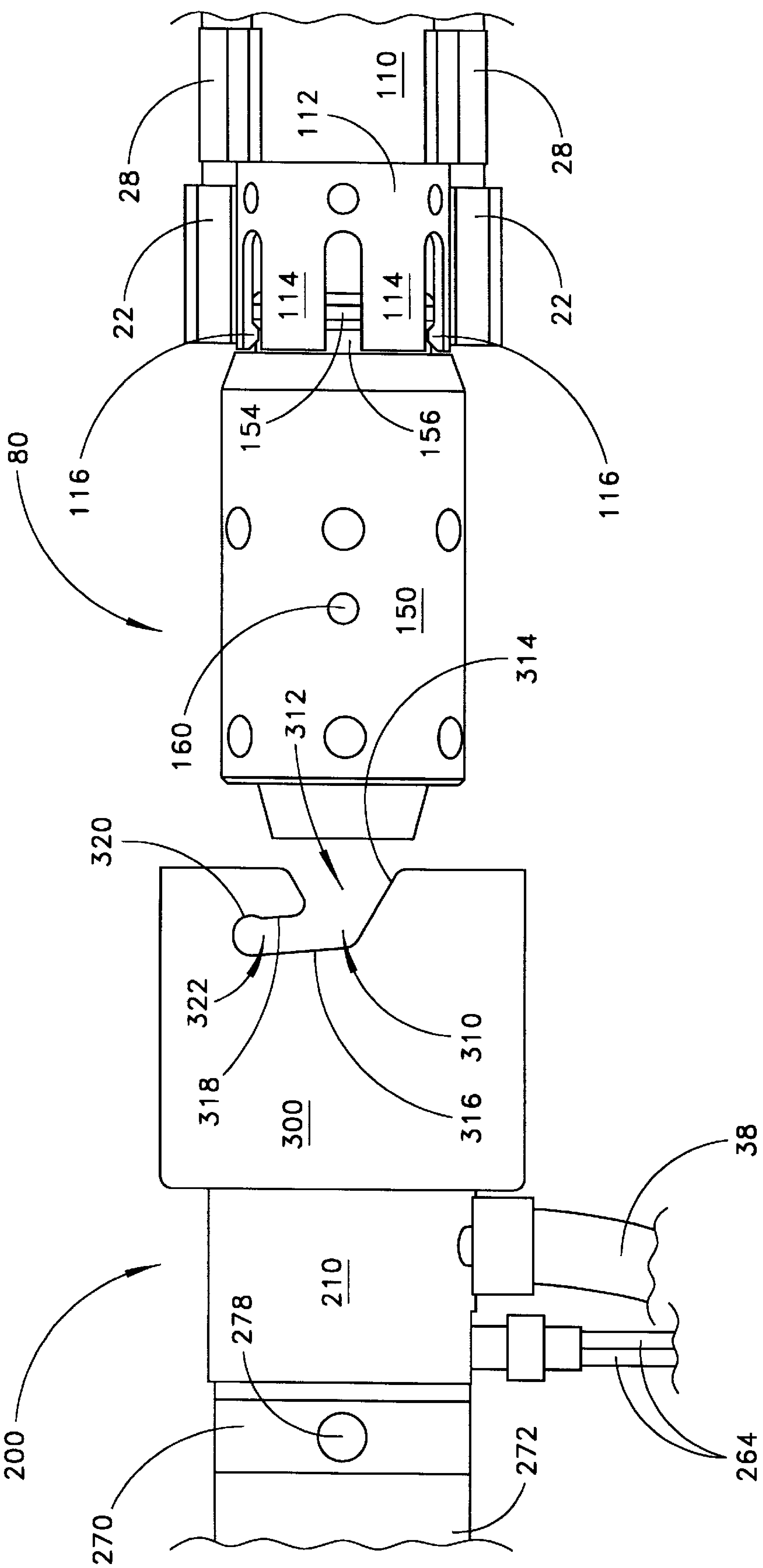
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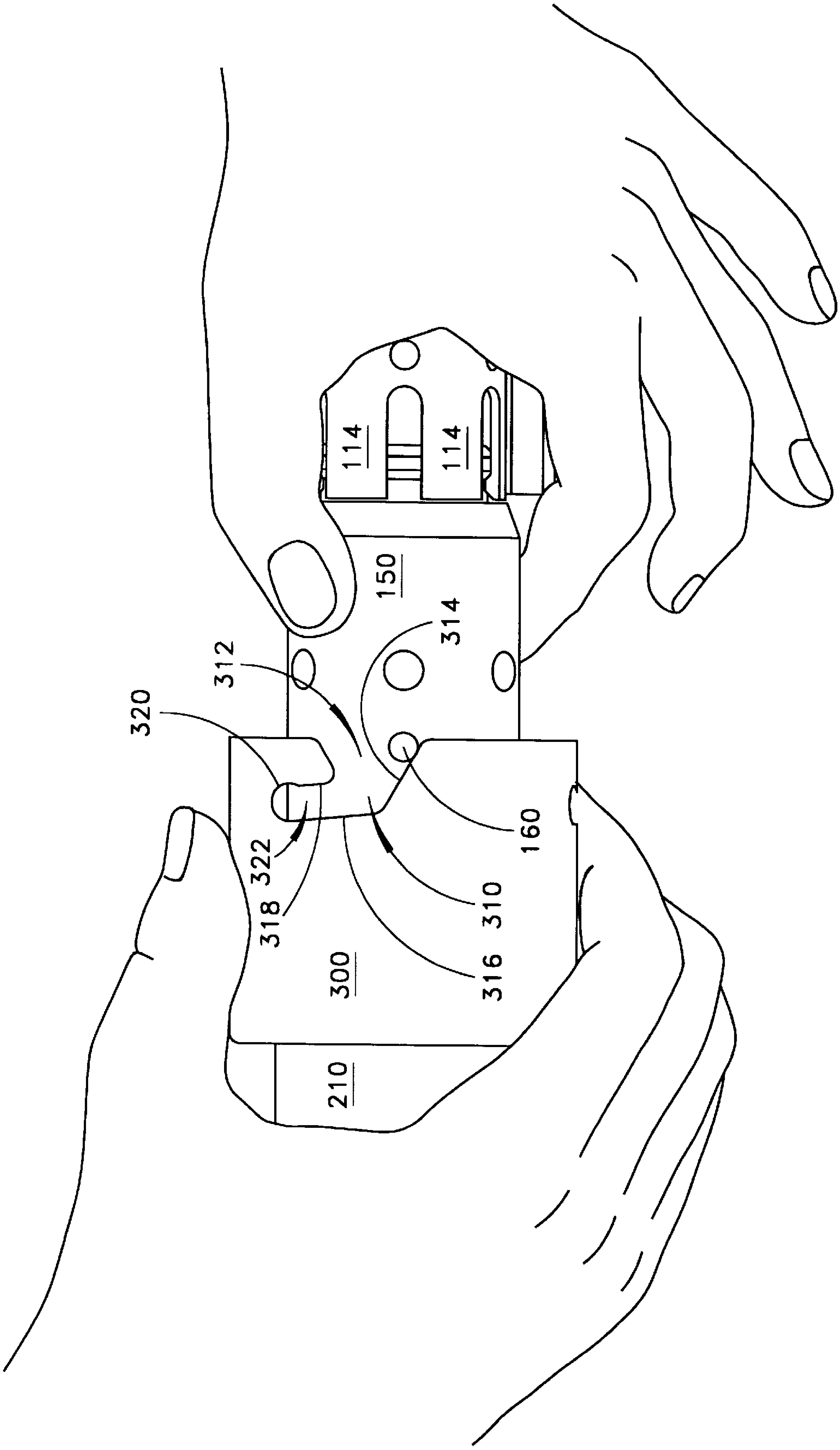
FIG.18



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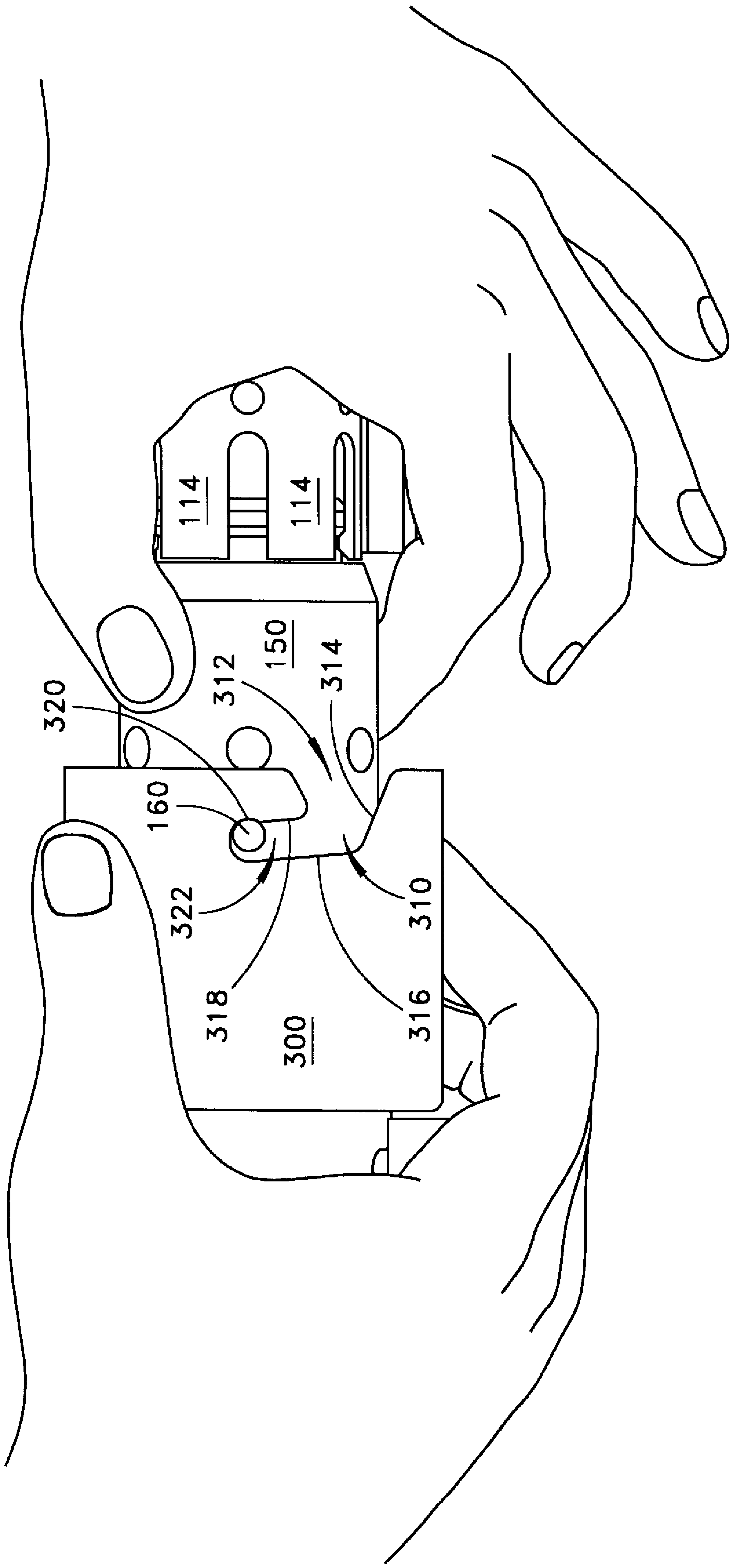

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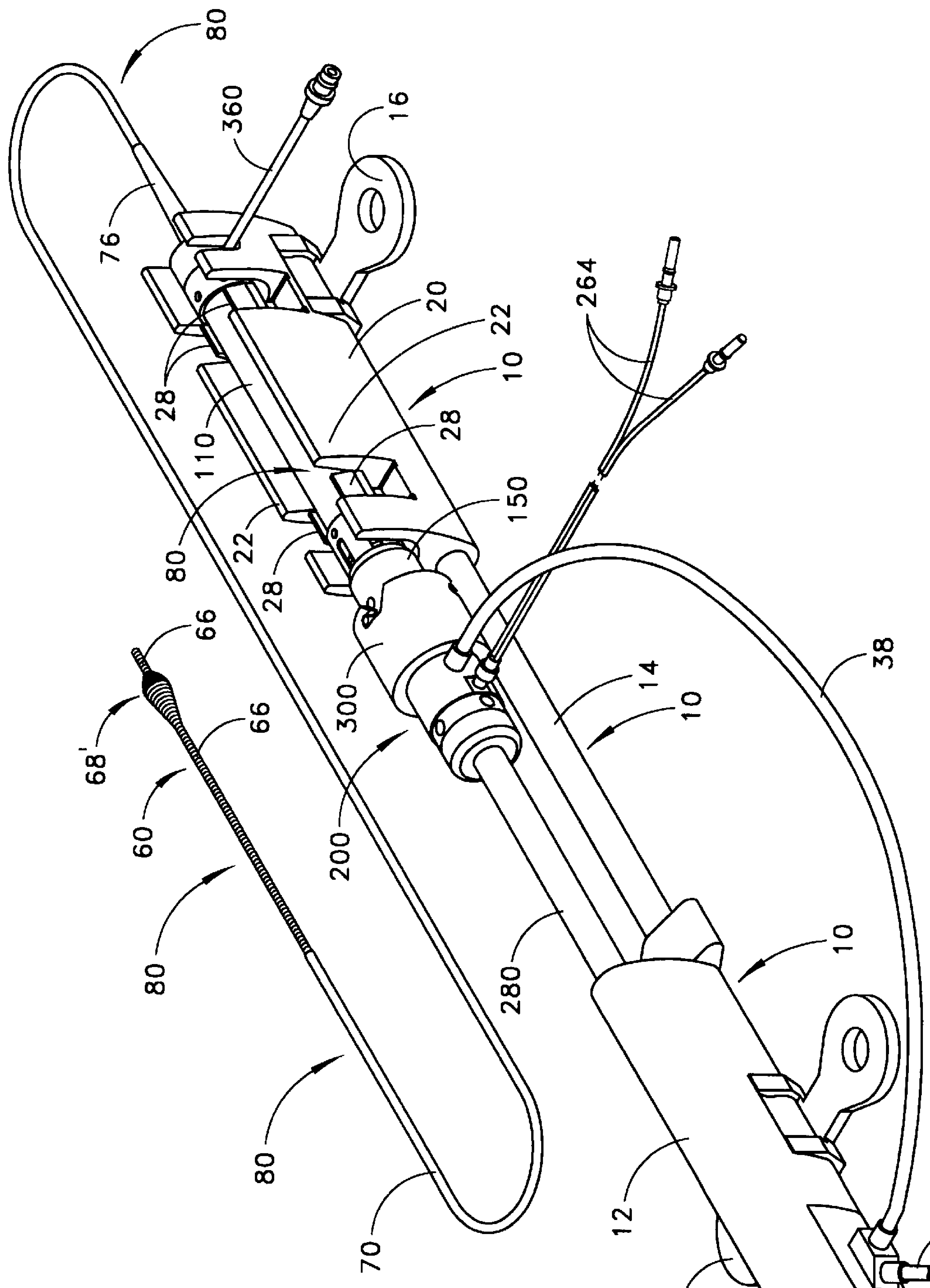
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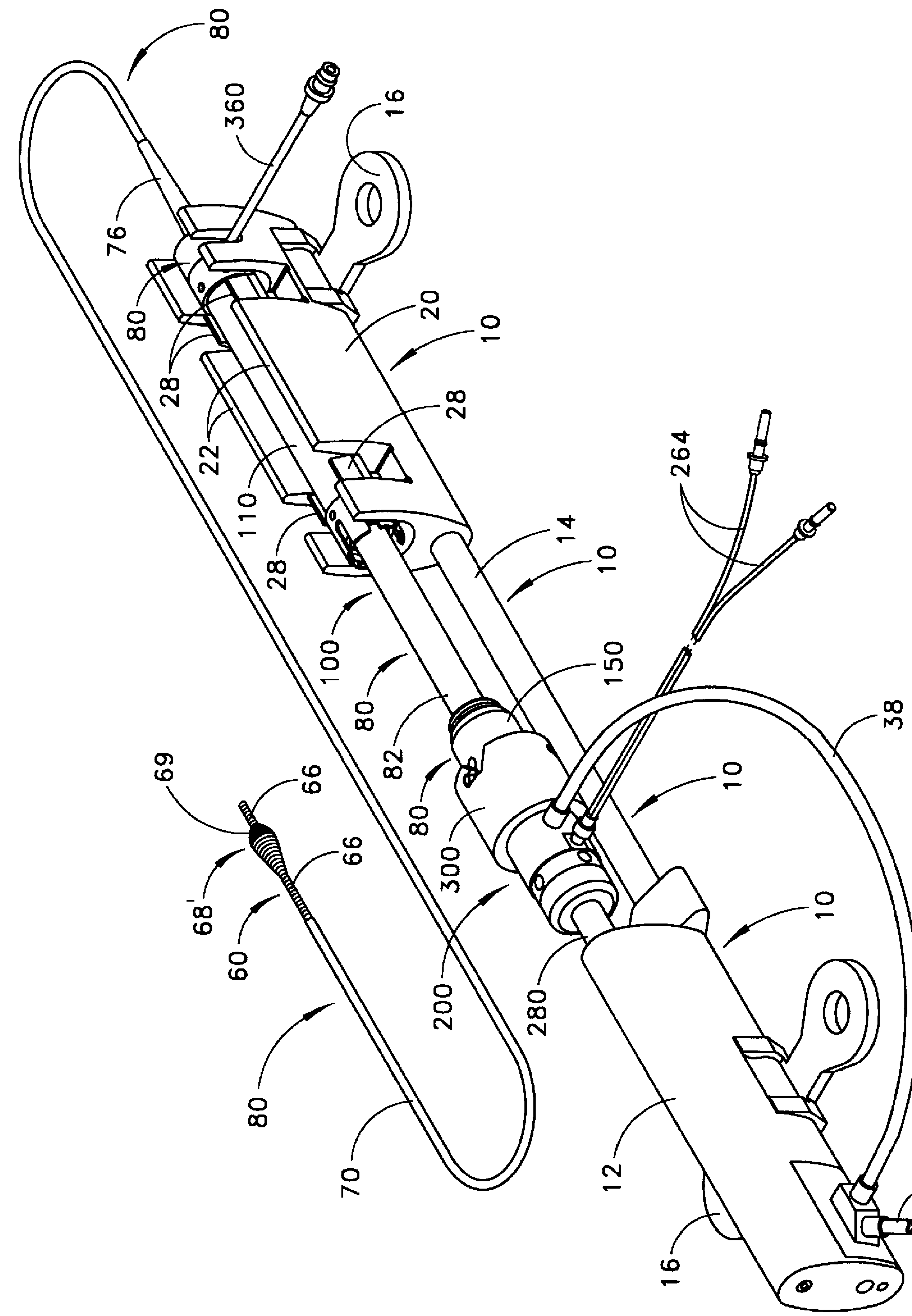
FIG. 21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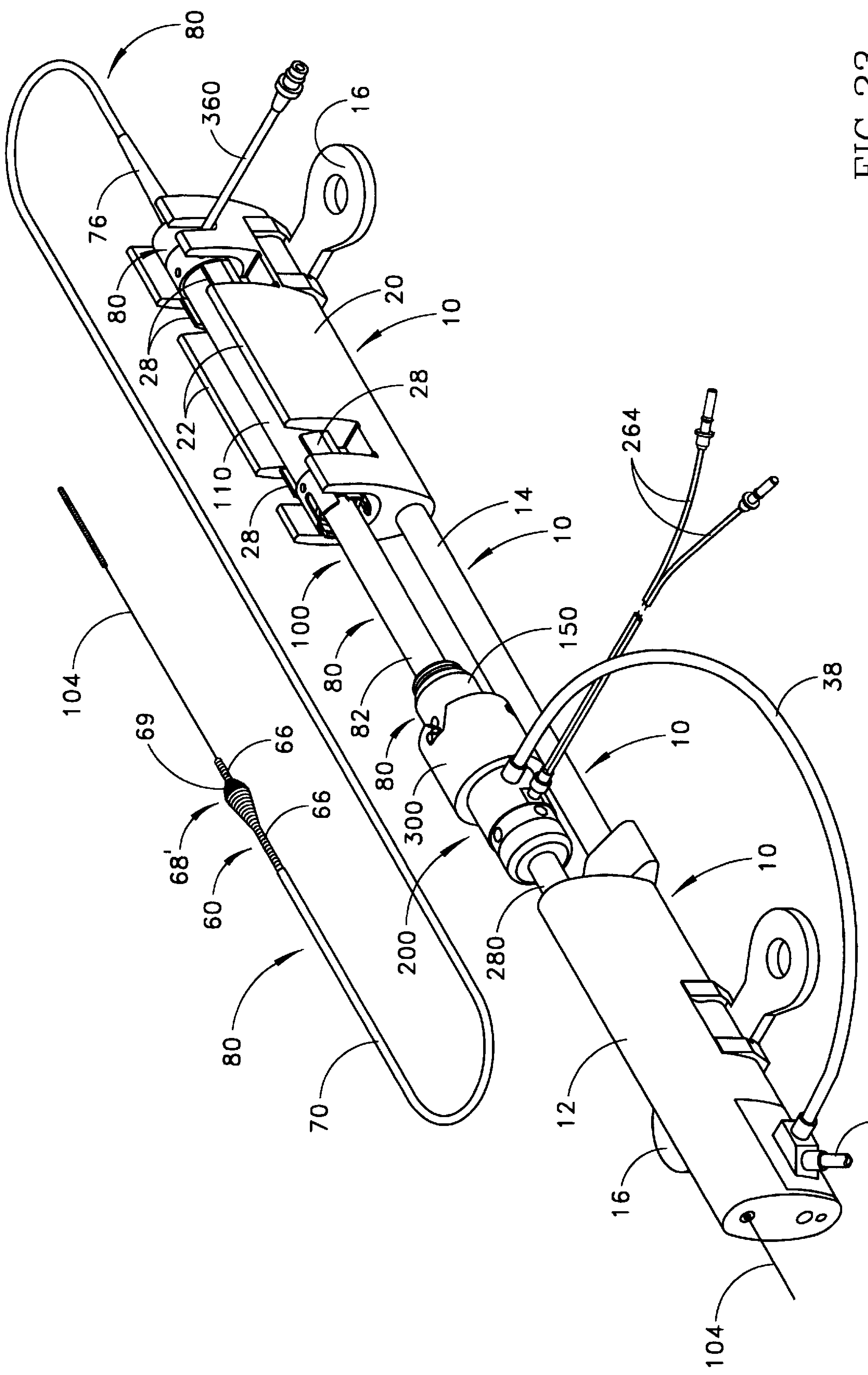
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FIG. 23

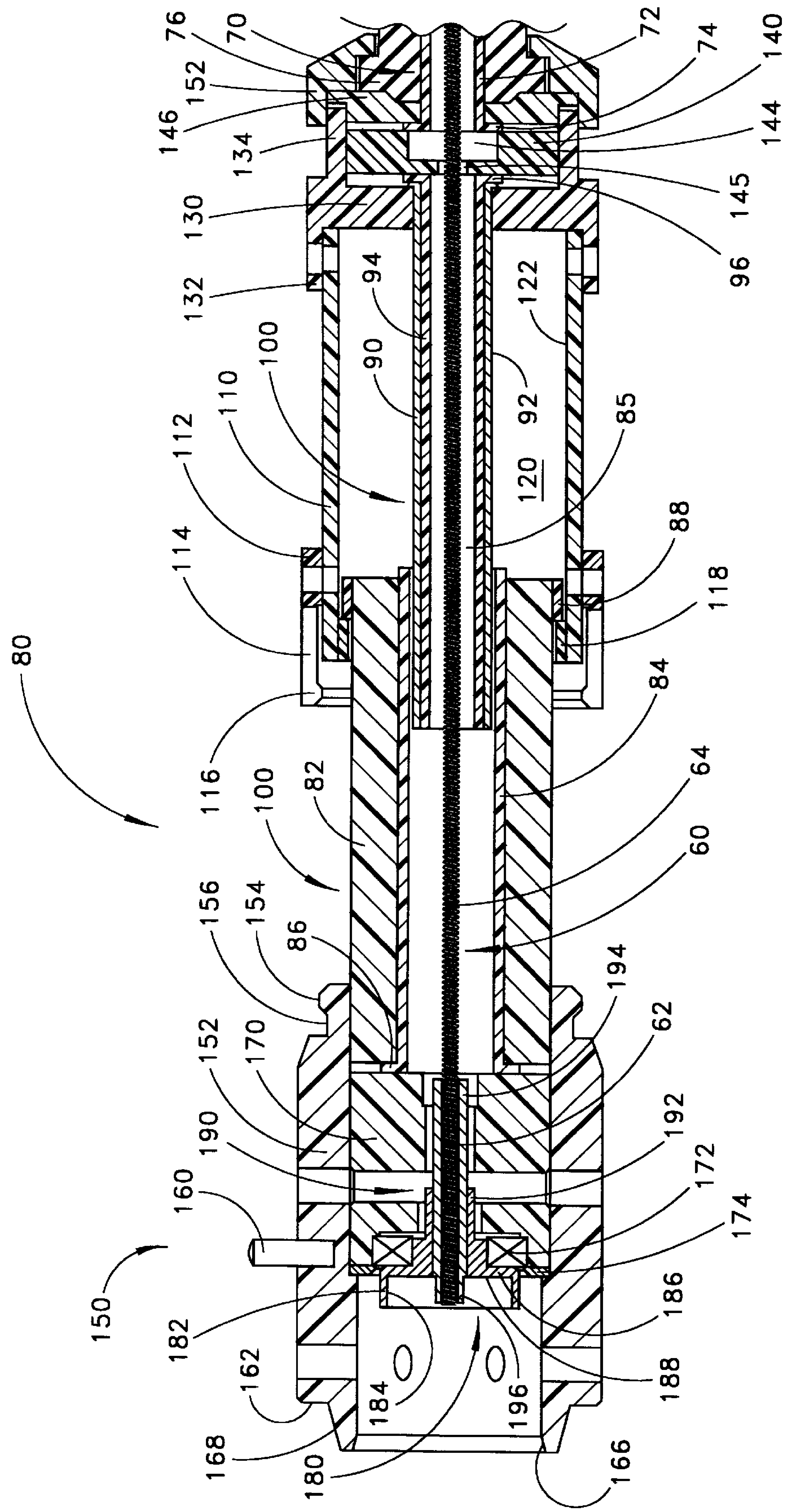
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FIG.24

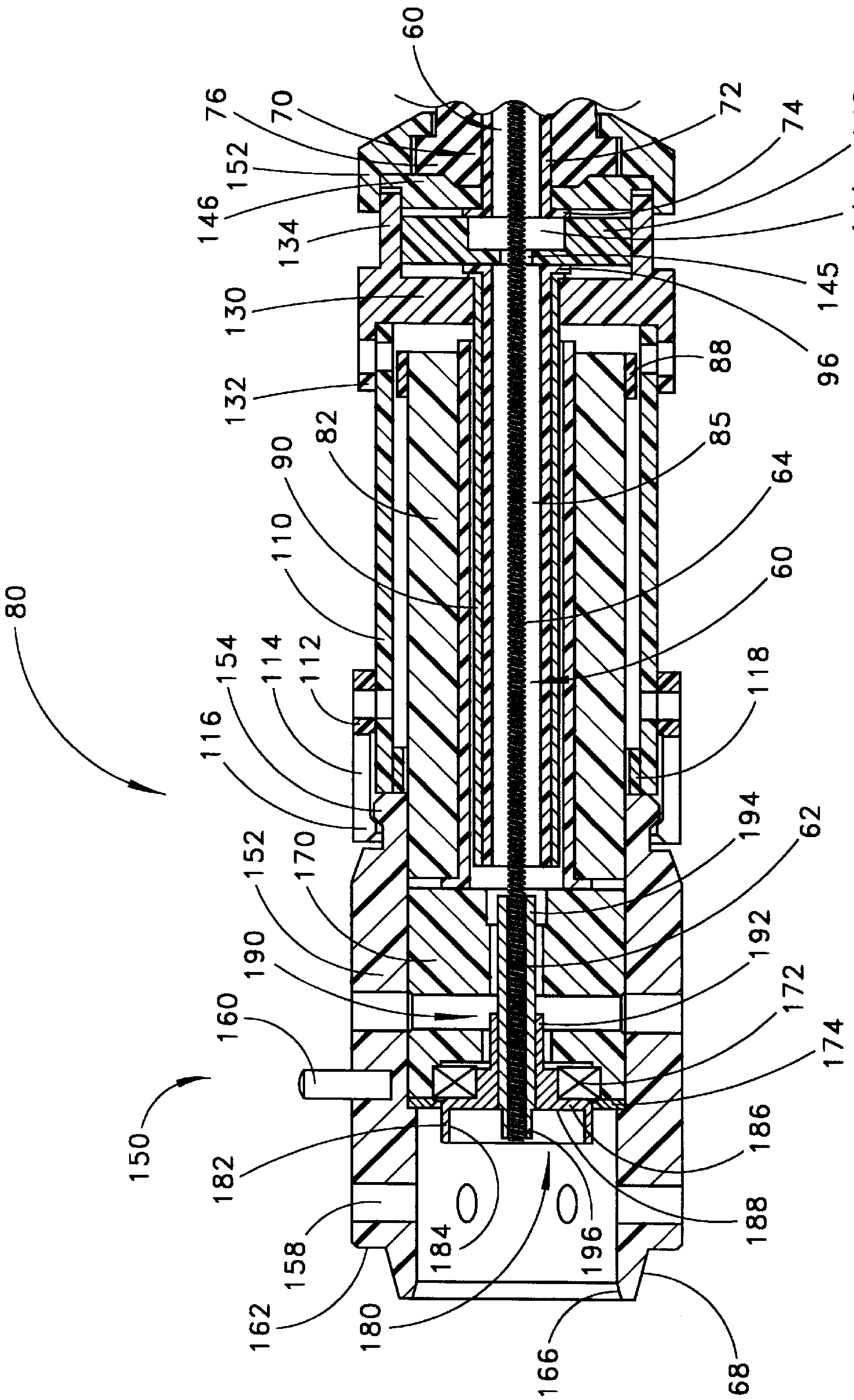
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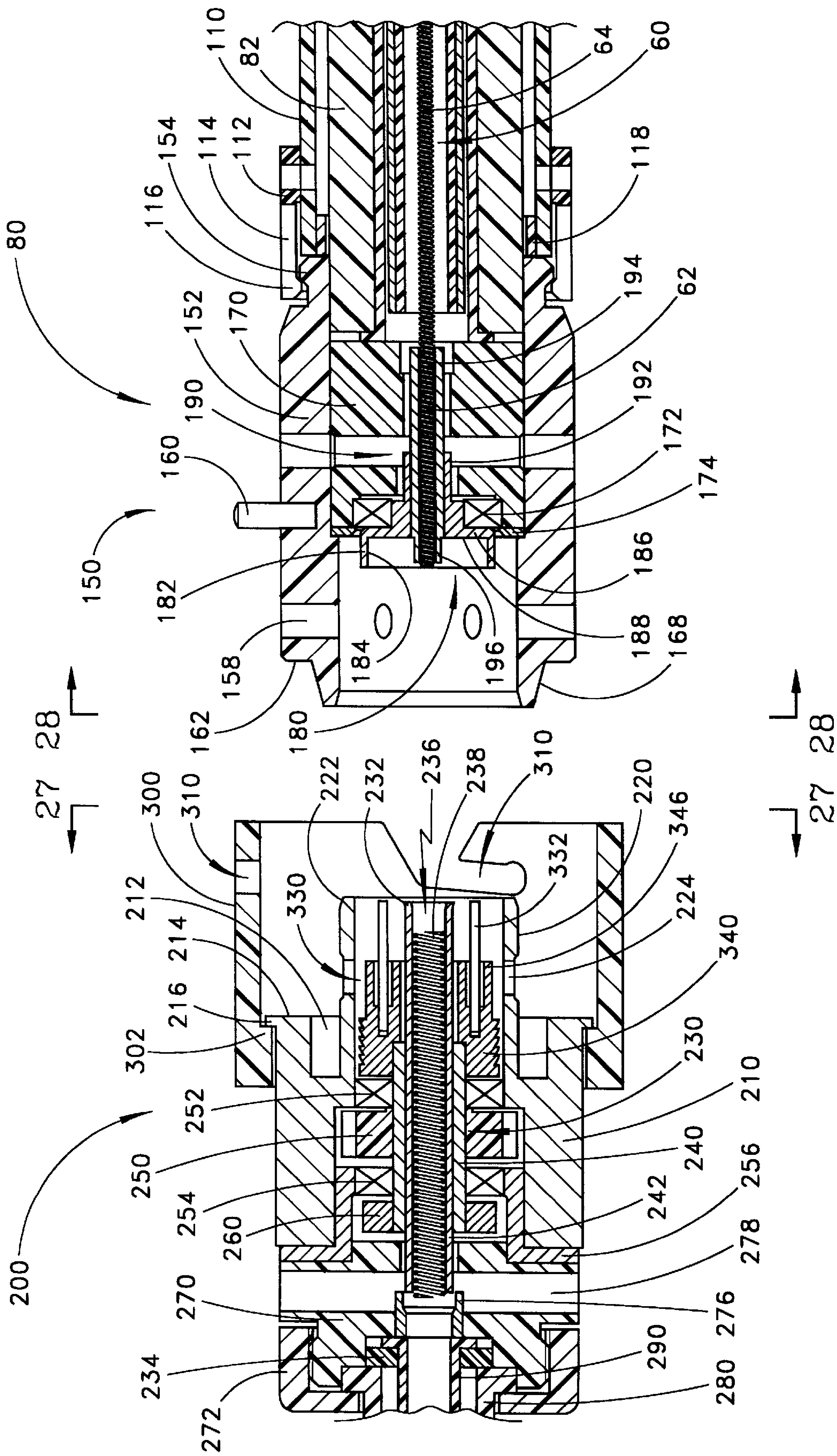
FIG. 25



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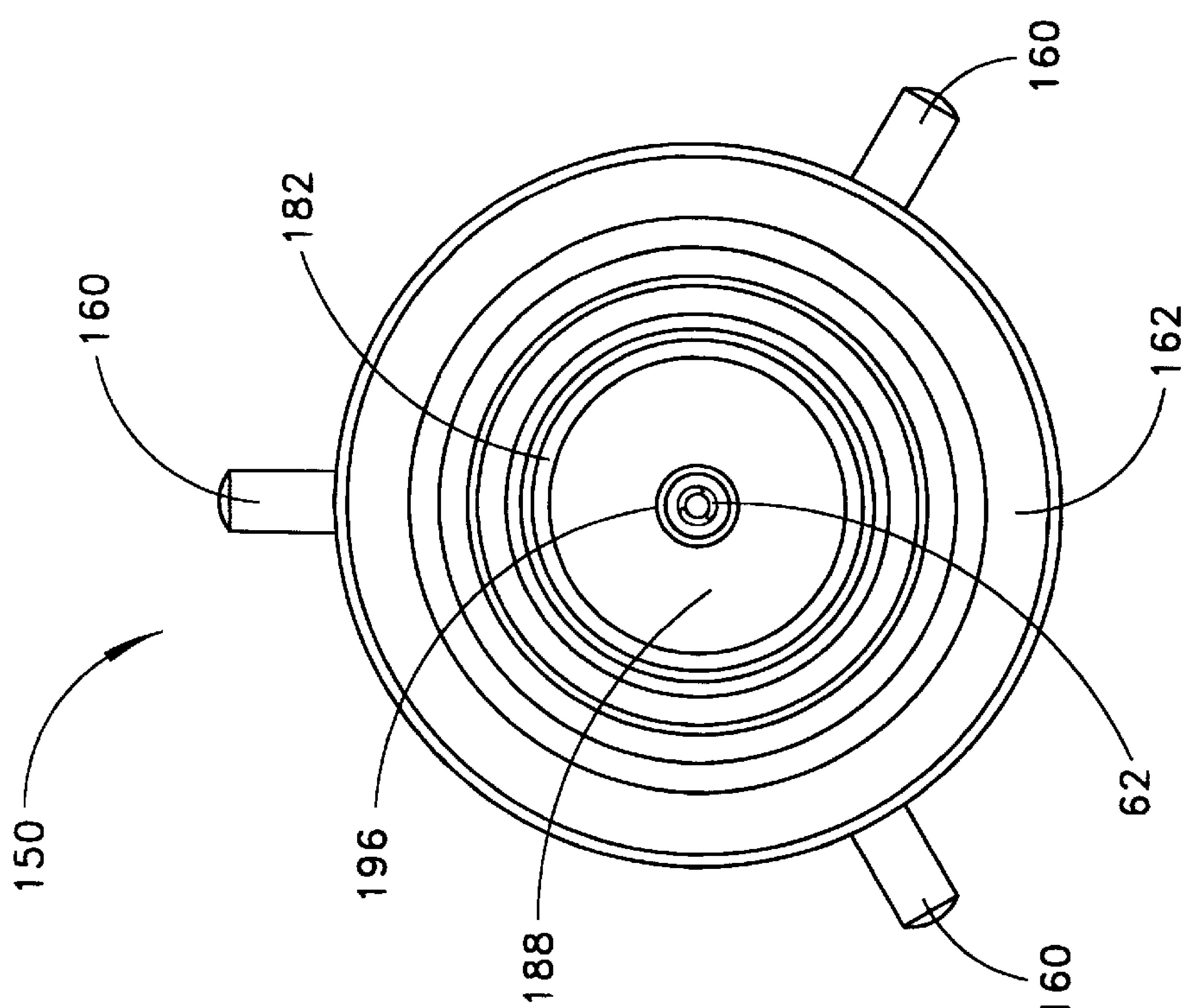
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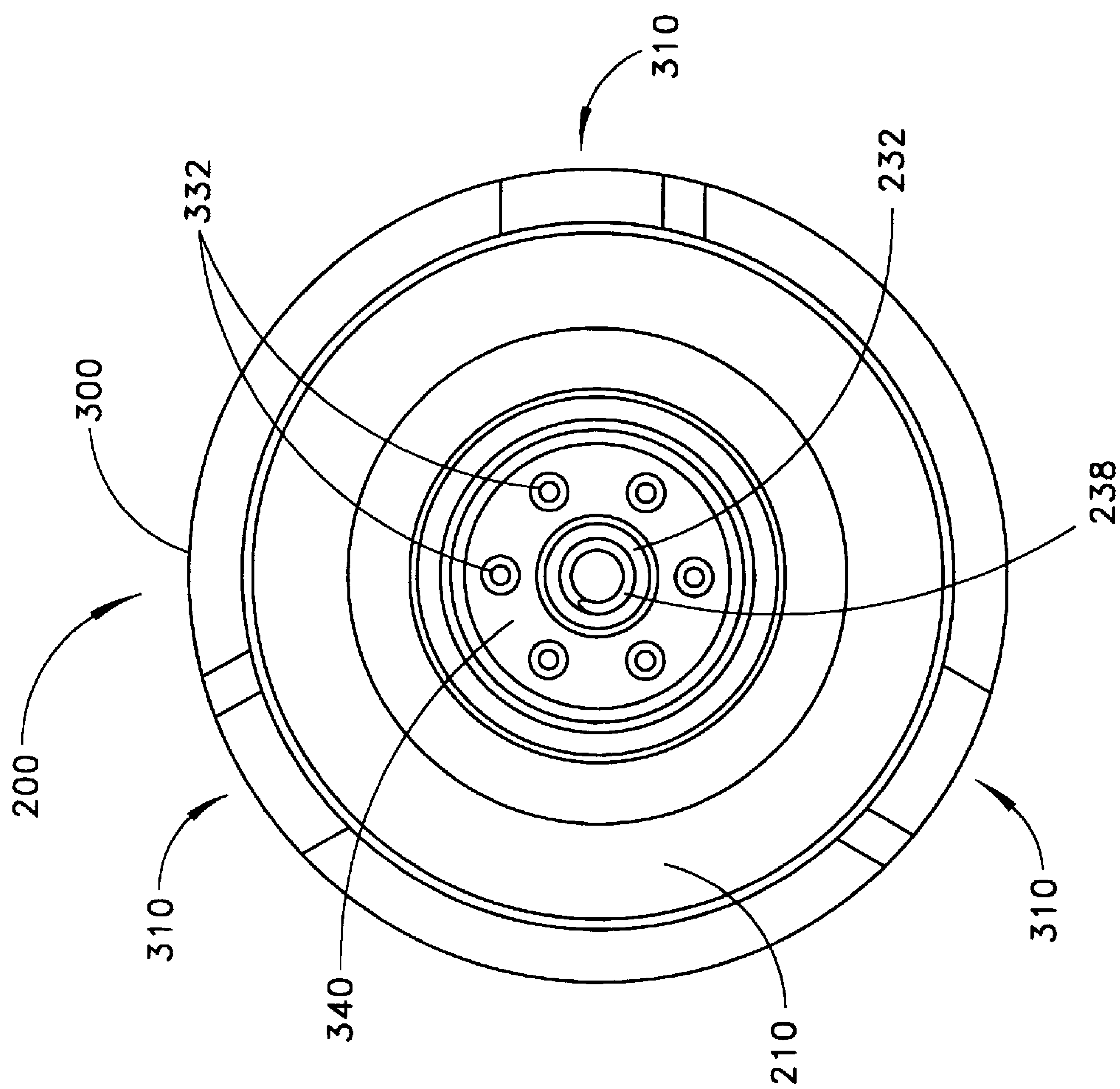
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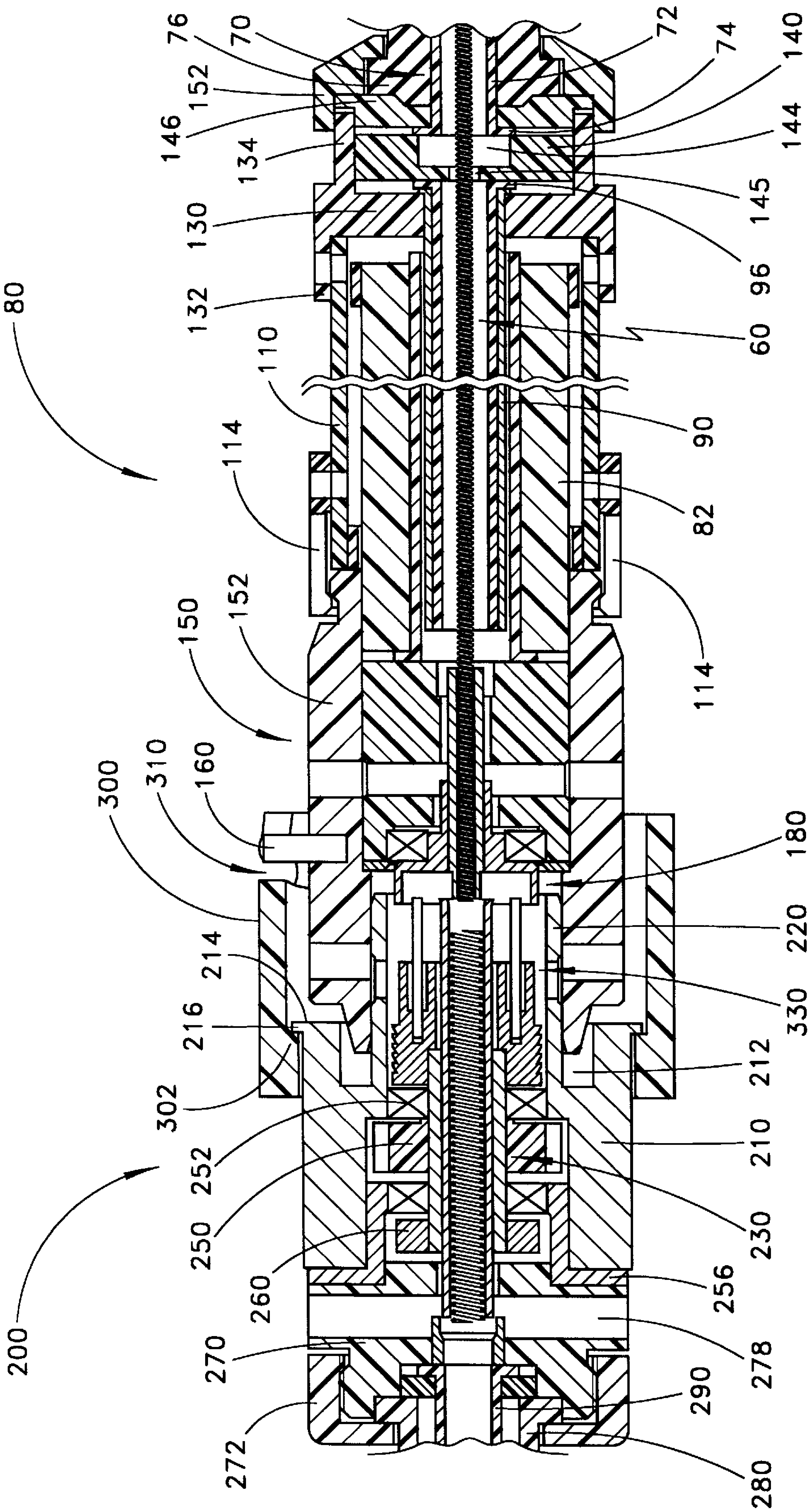
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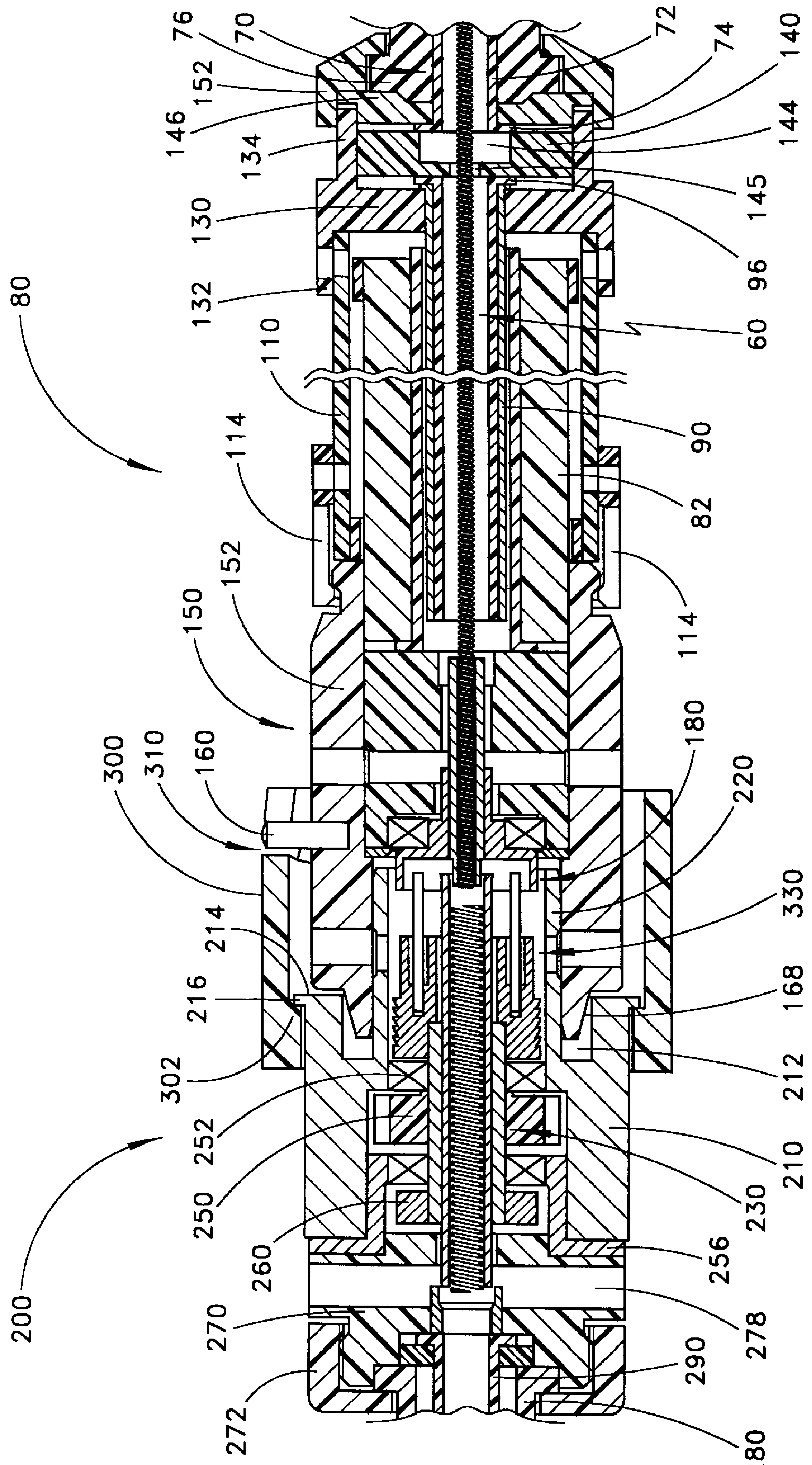

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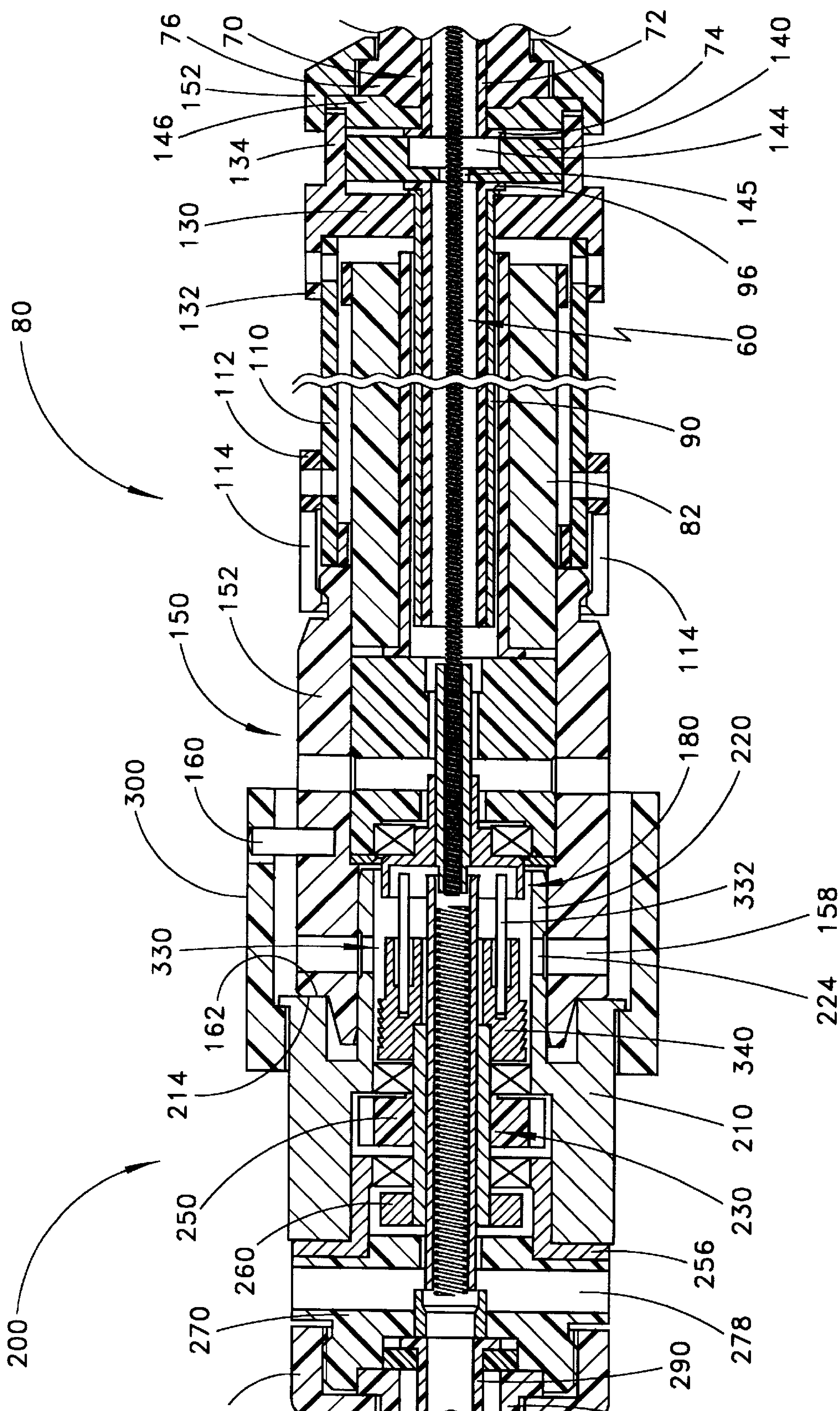
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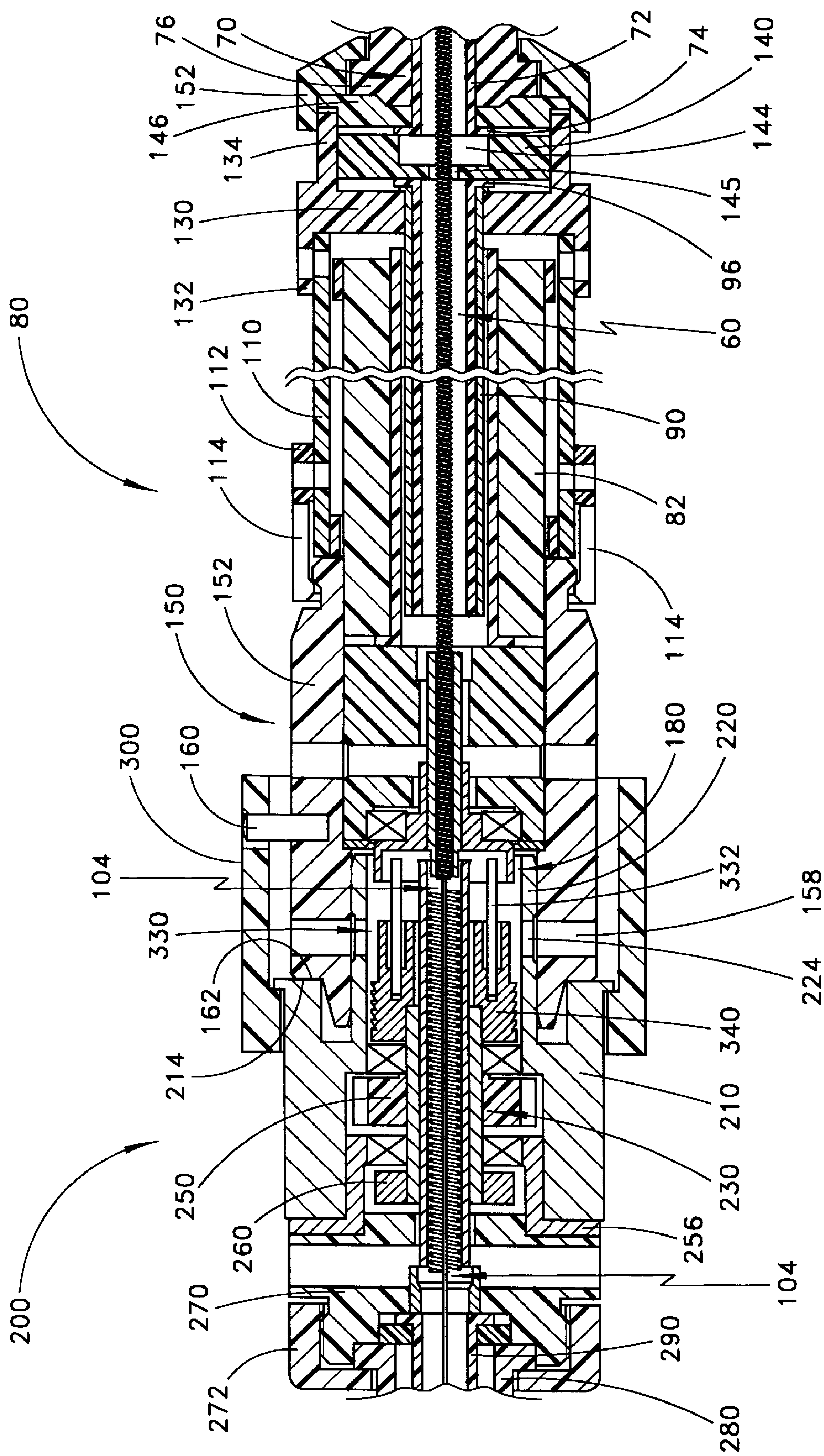
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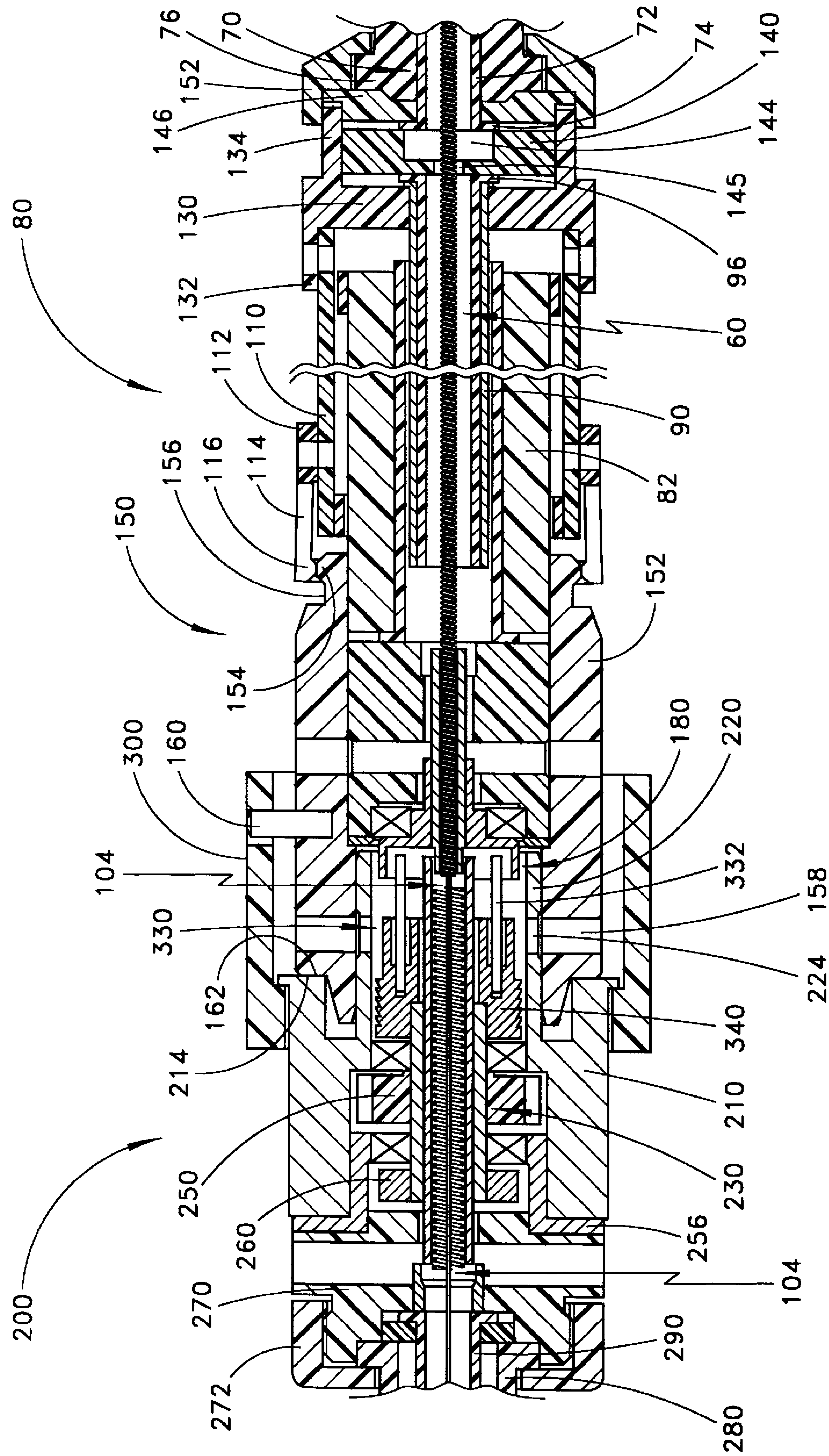
FIG. 32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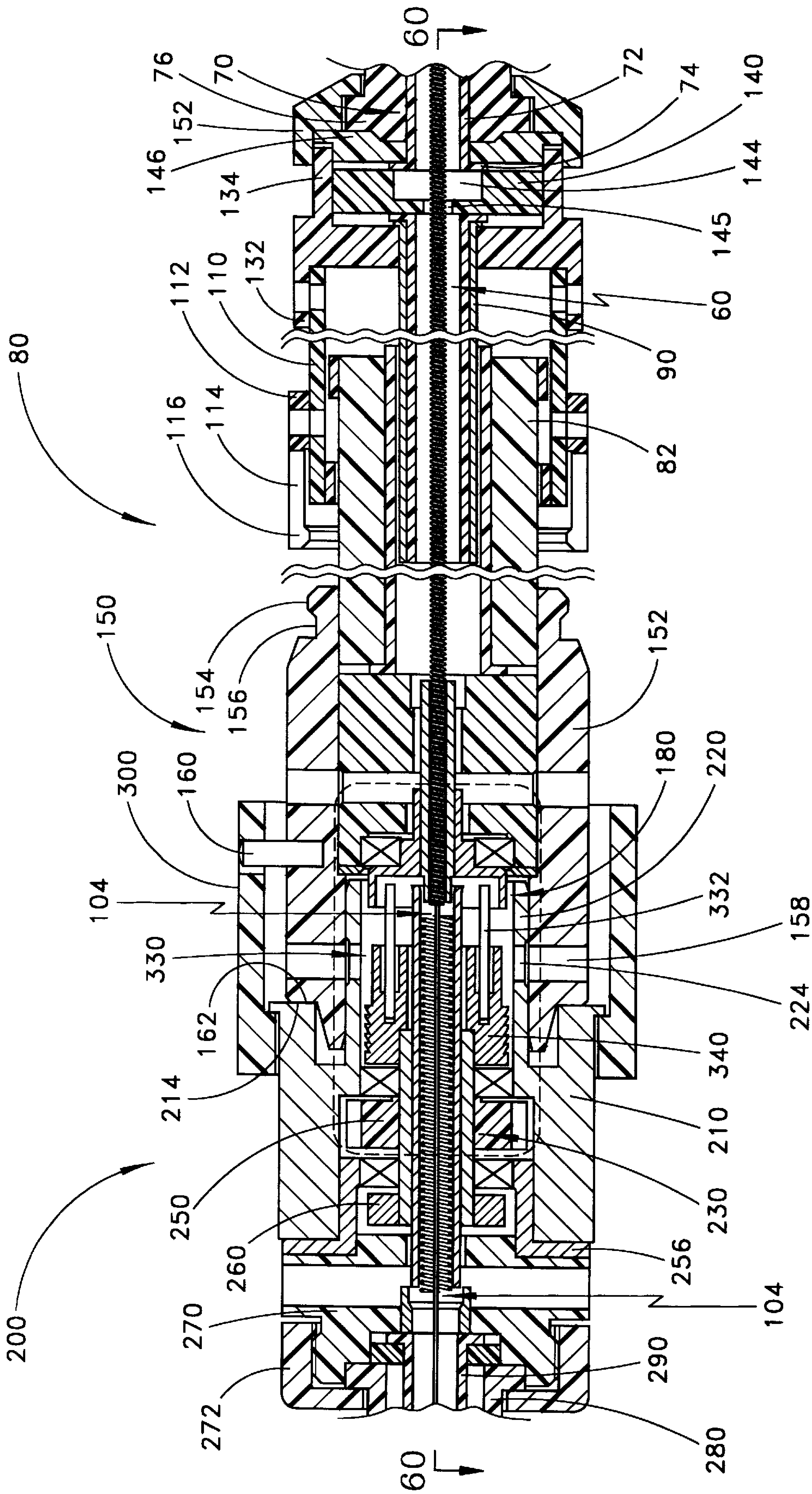
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FIG. 34

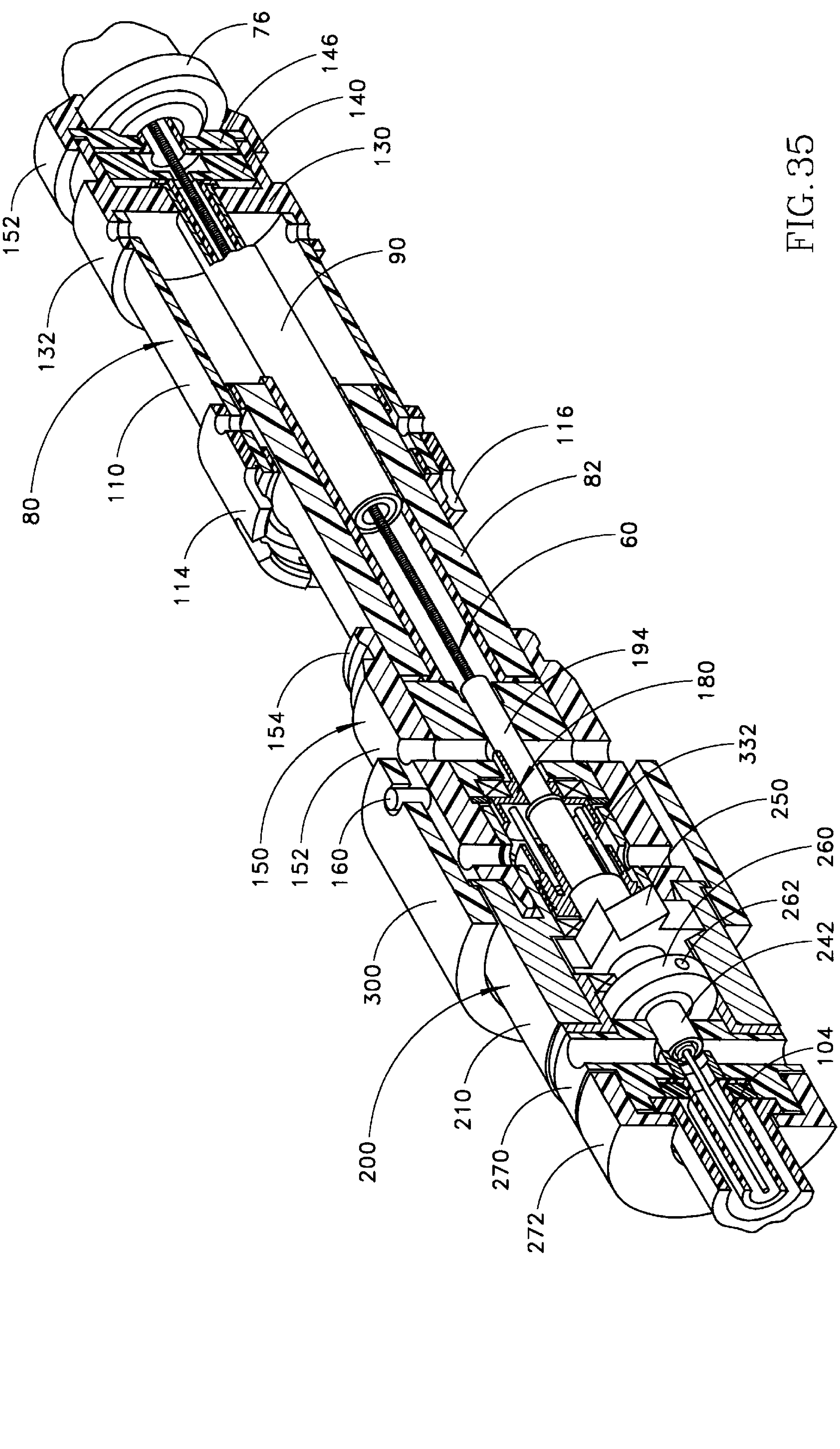
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FIG. 35

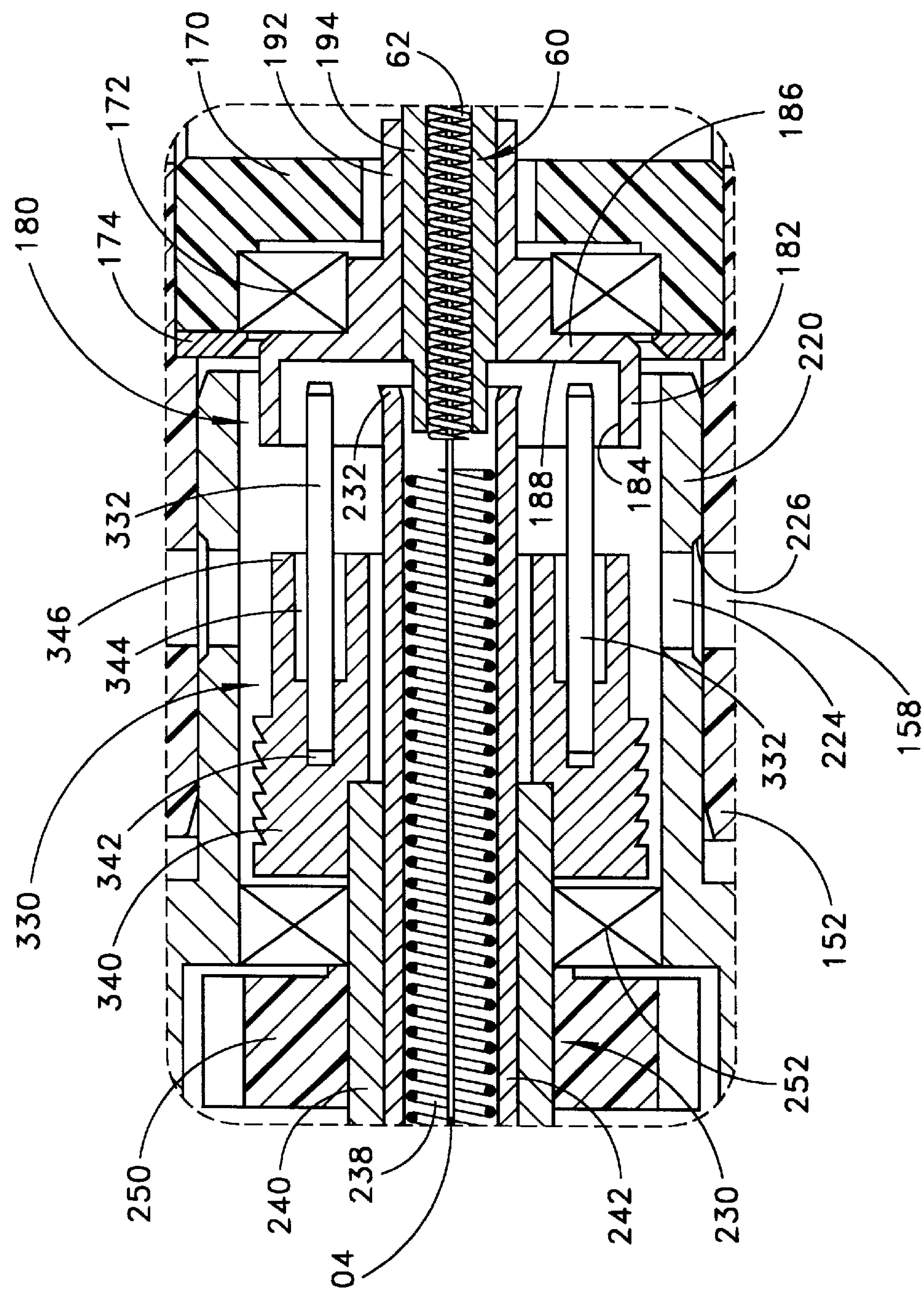
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FIG. 36

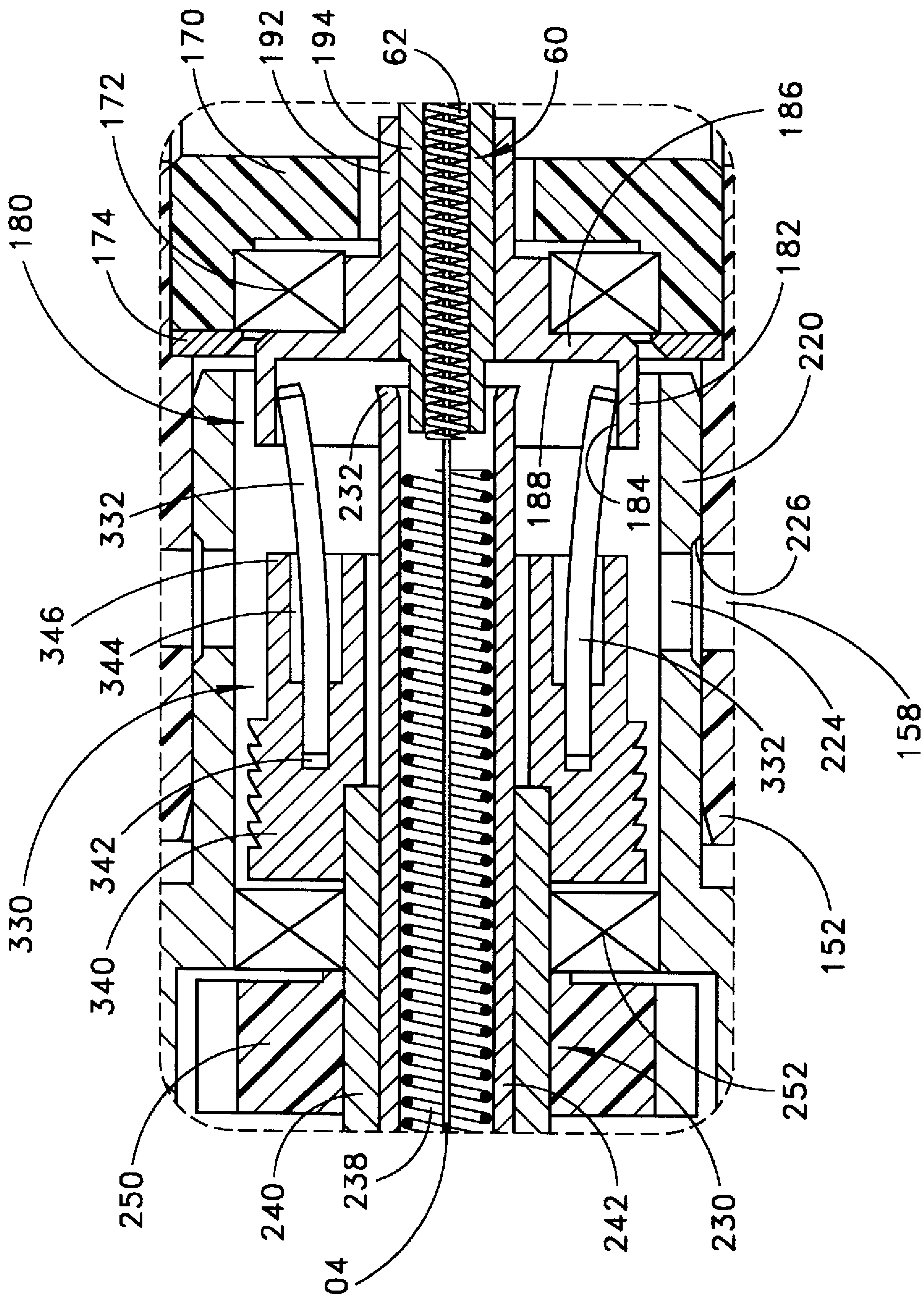
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FIG. 37

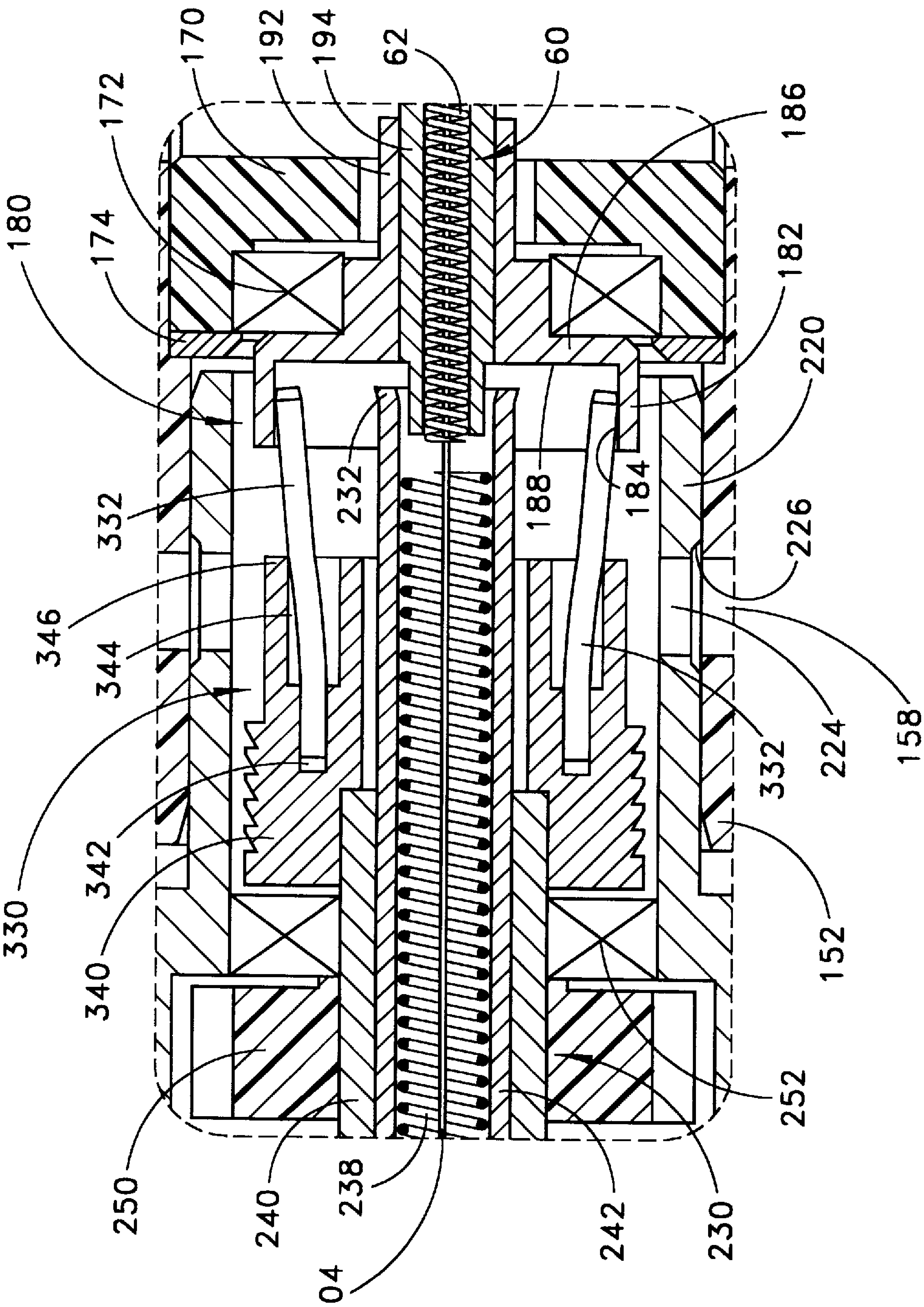
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FIG. 38

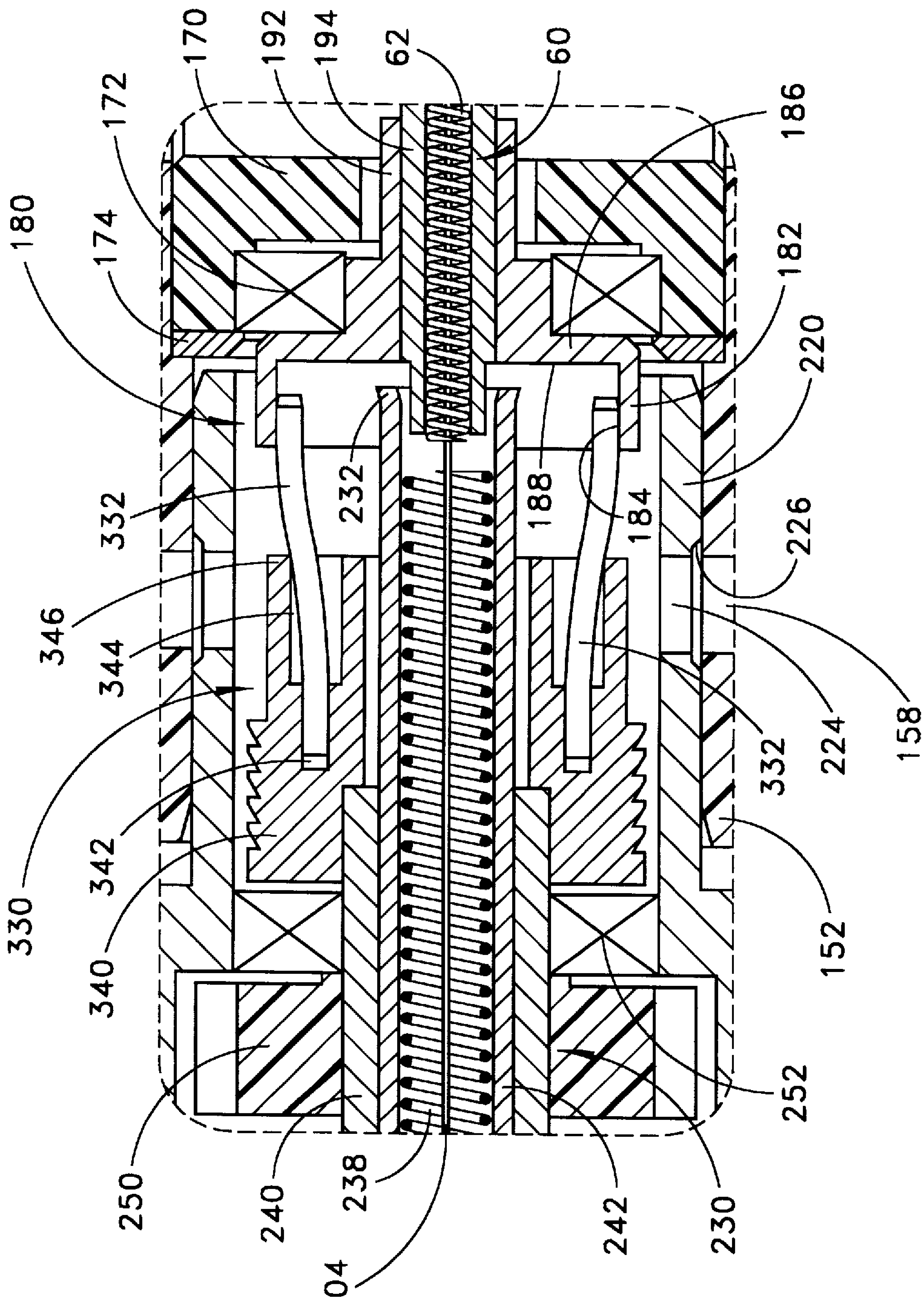
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FIG. 39

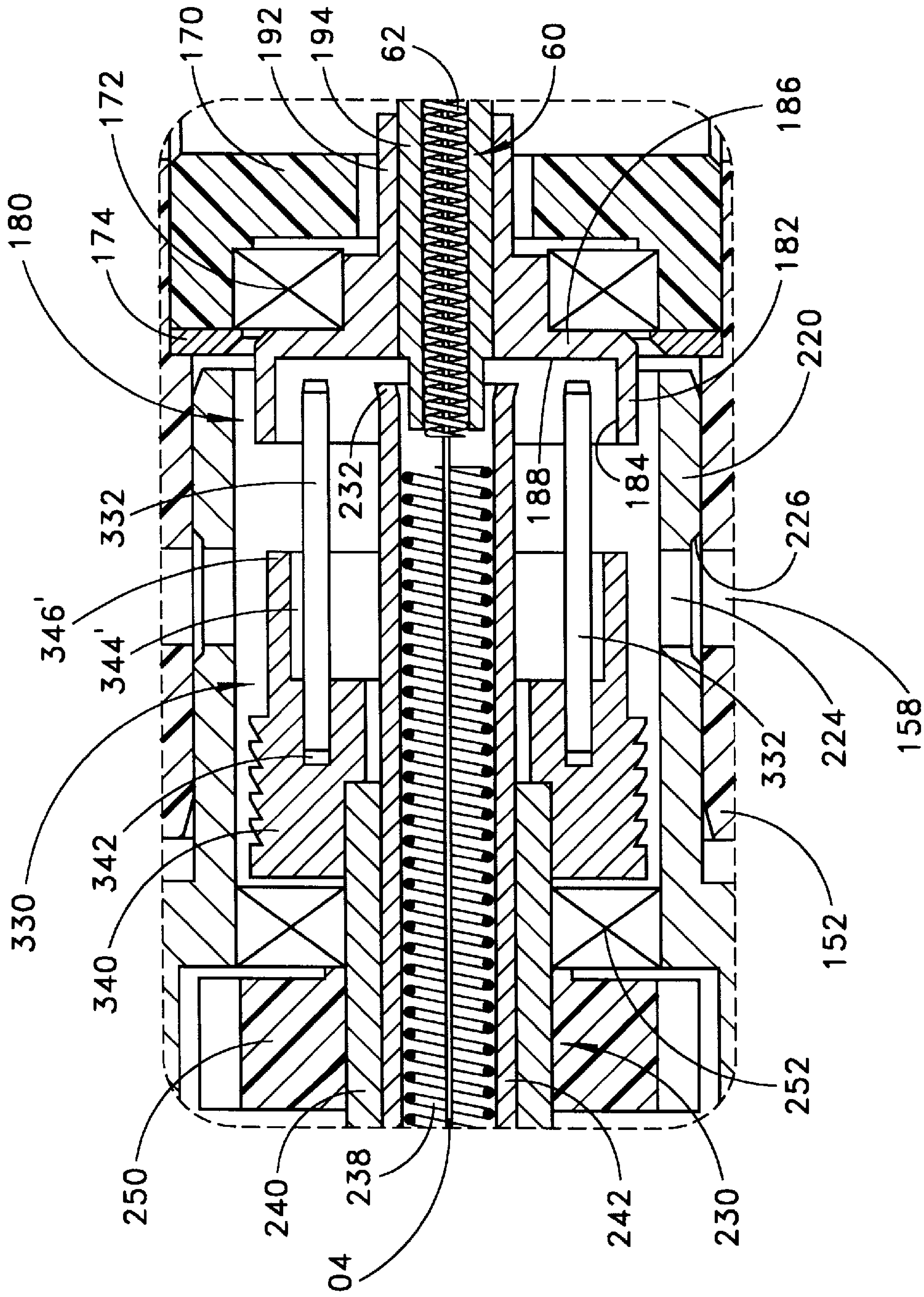
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FIG. 40

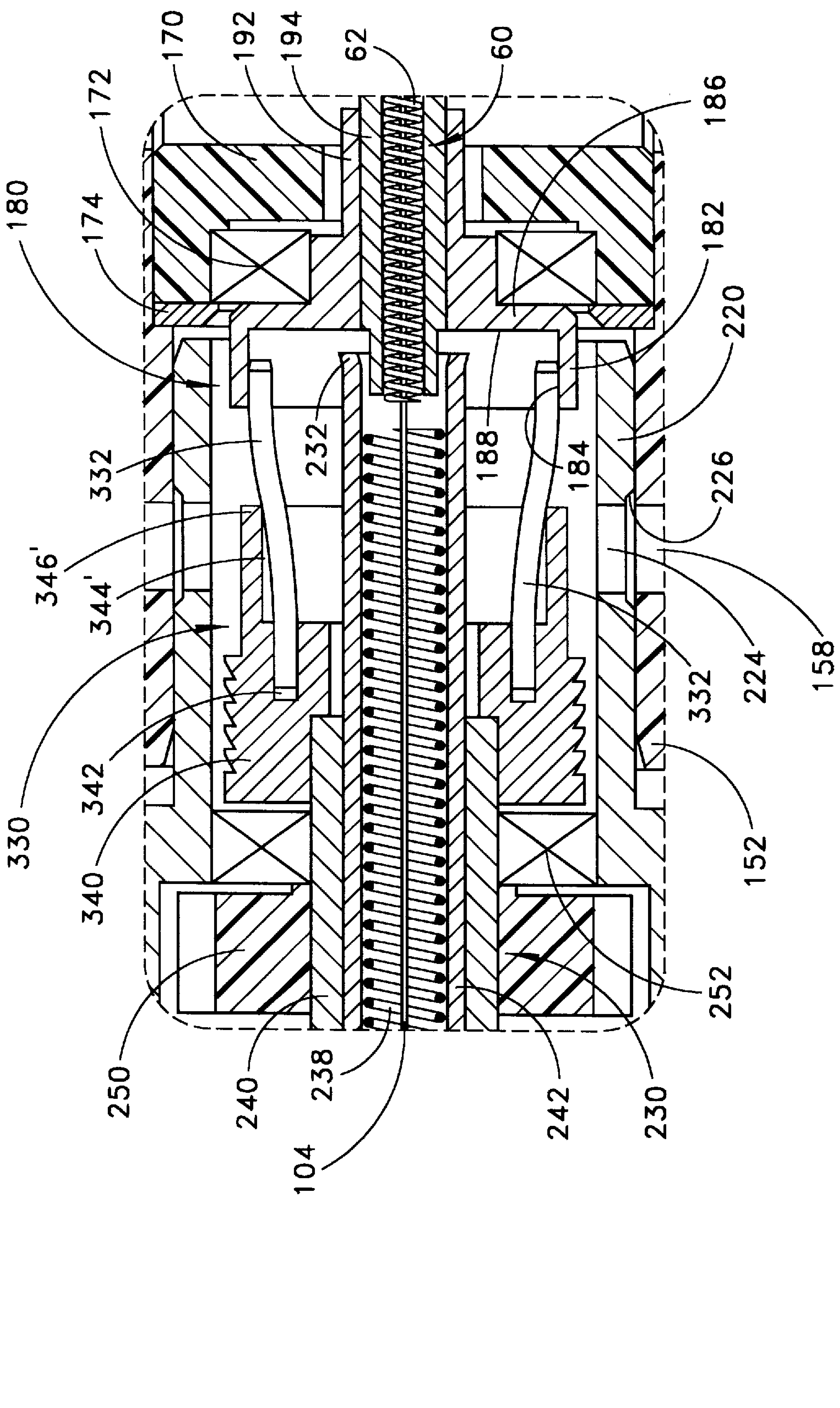
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FIG. 41

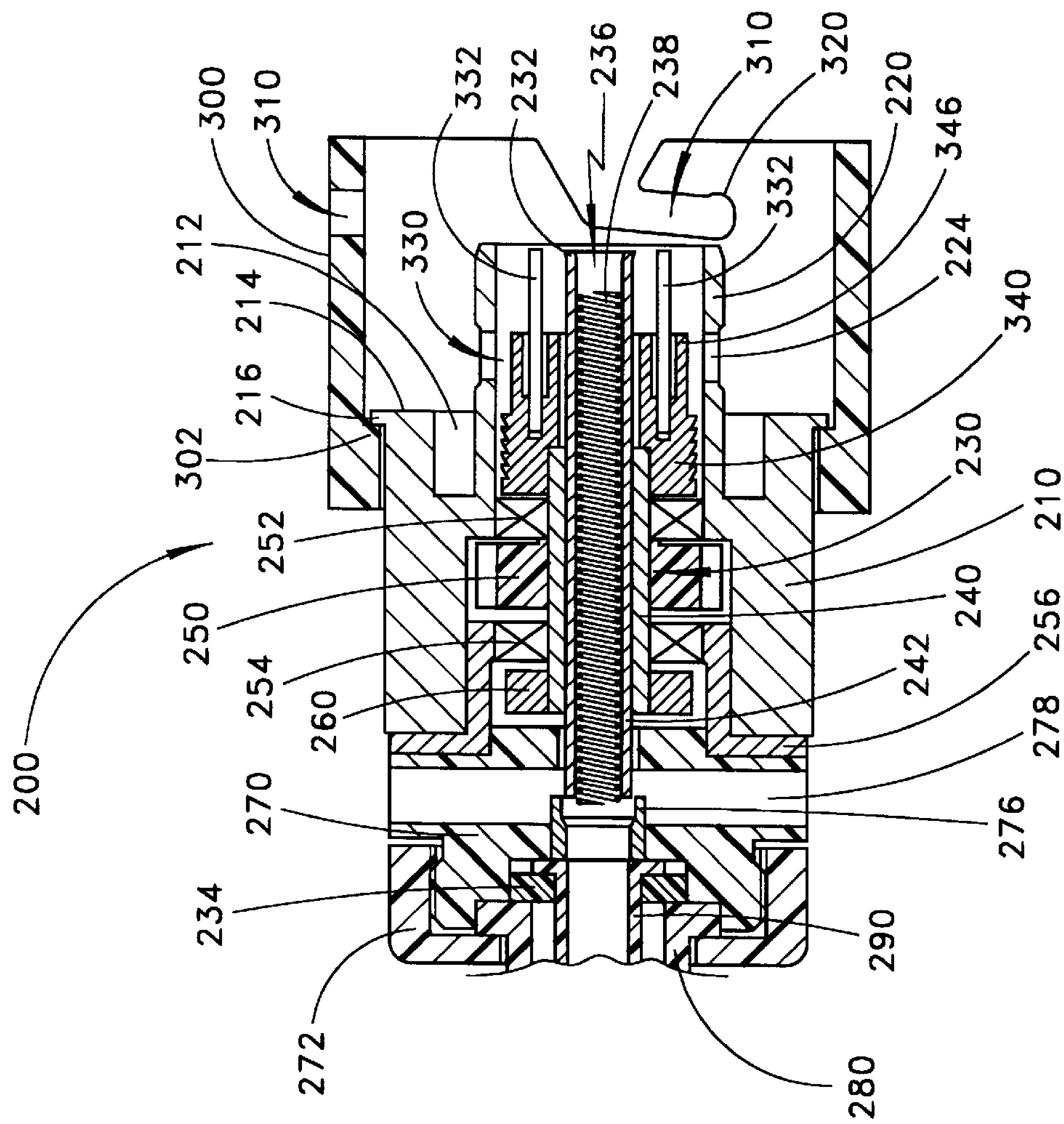
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FIG. 42

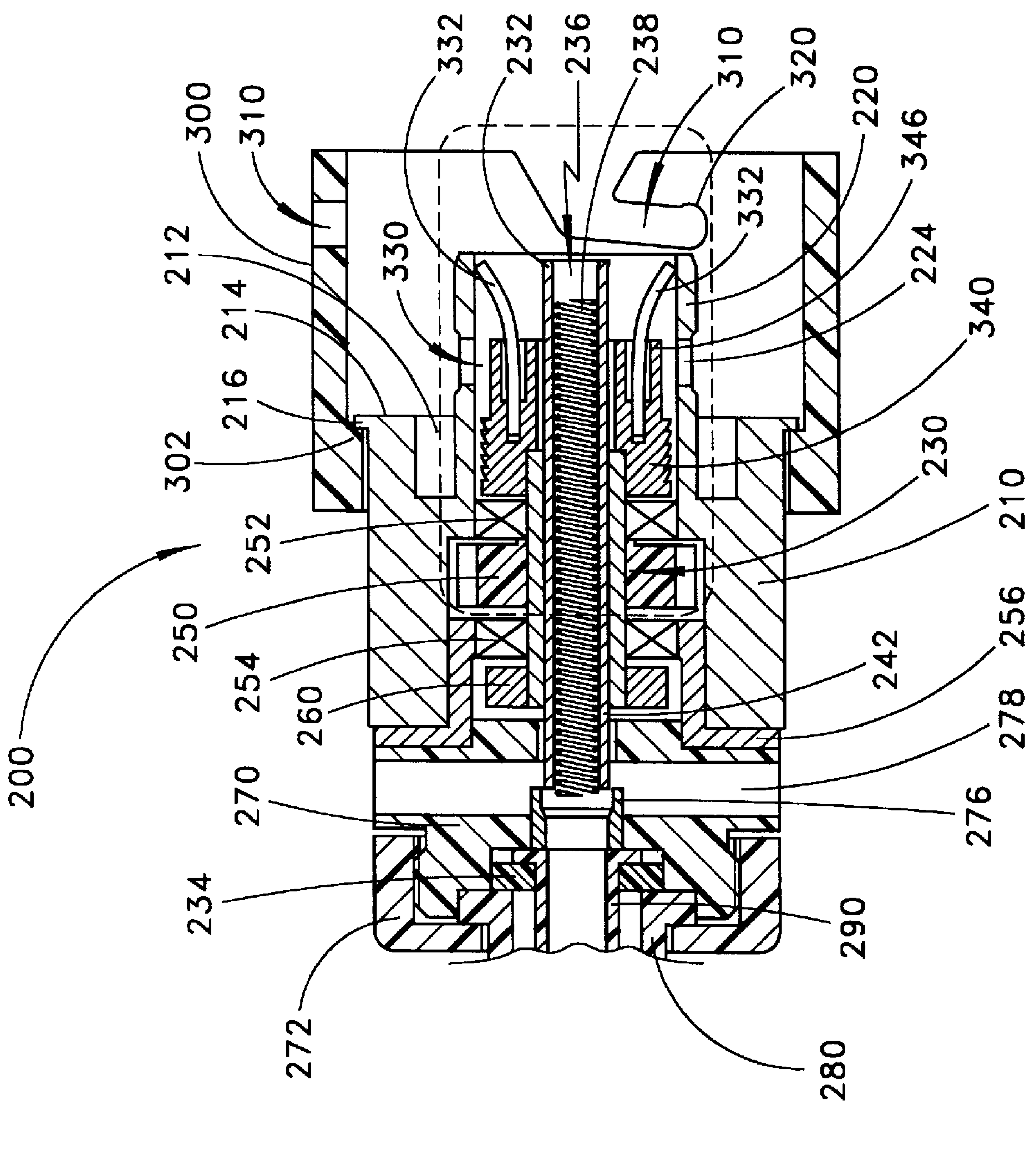
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FIG. 43

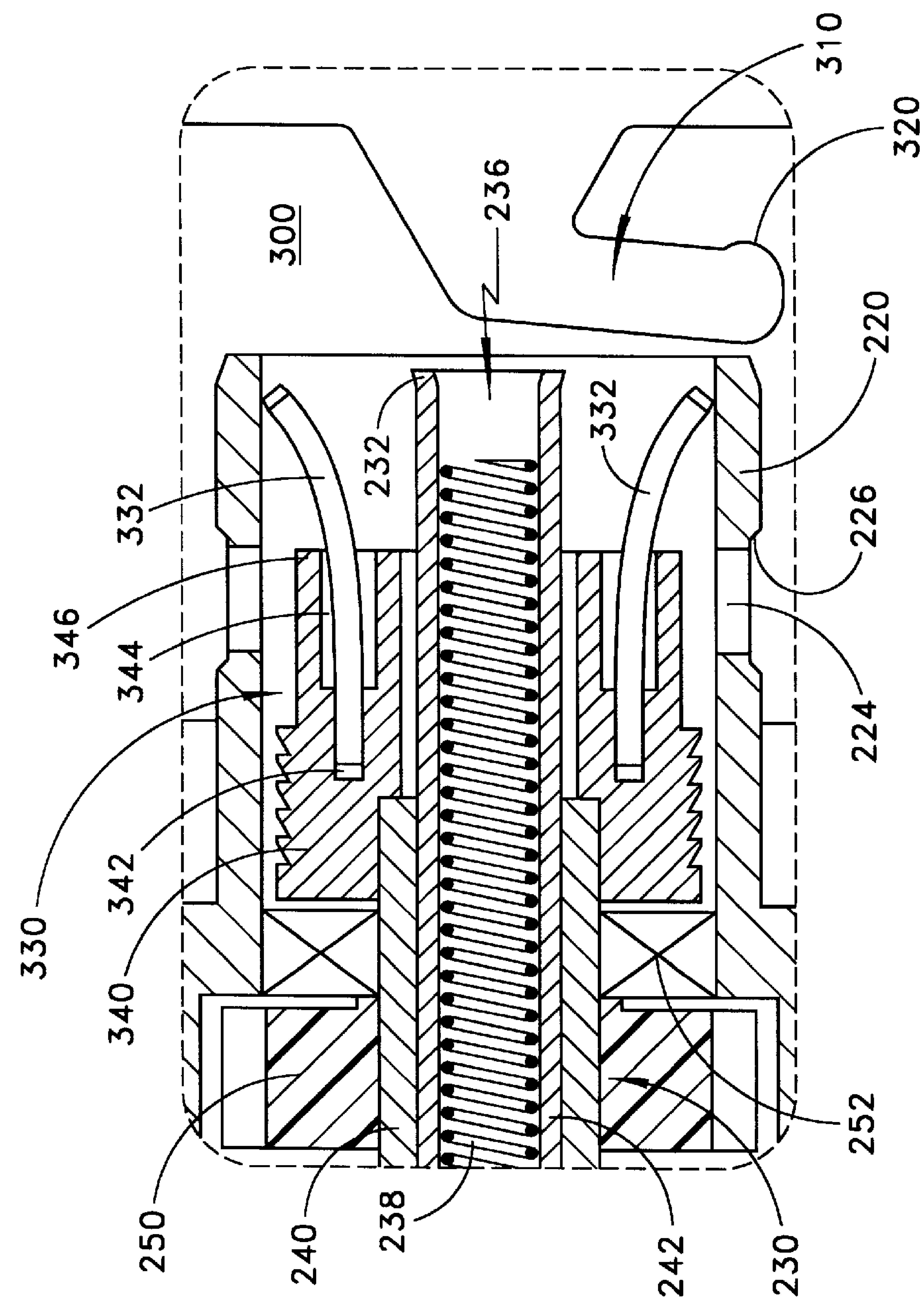
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FIG. 44

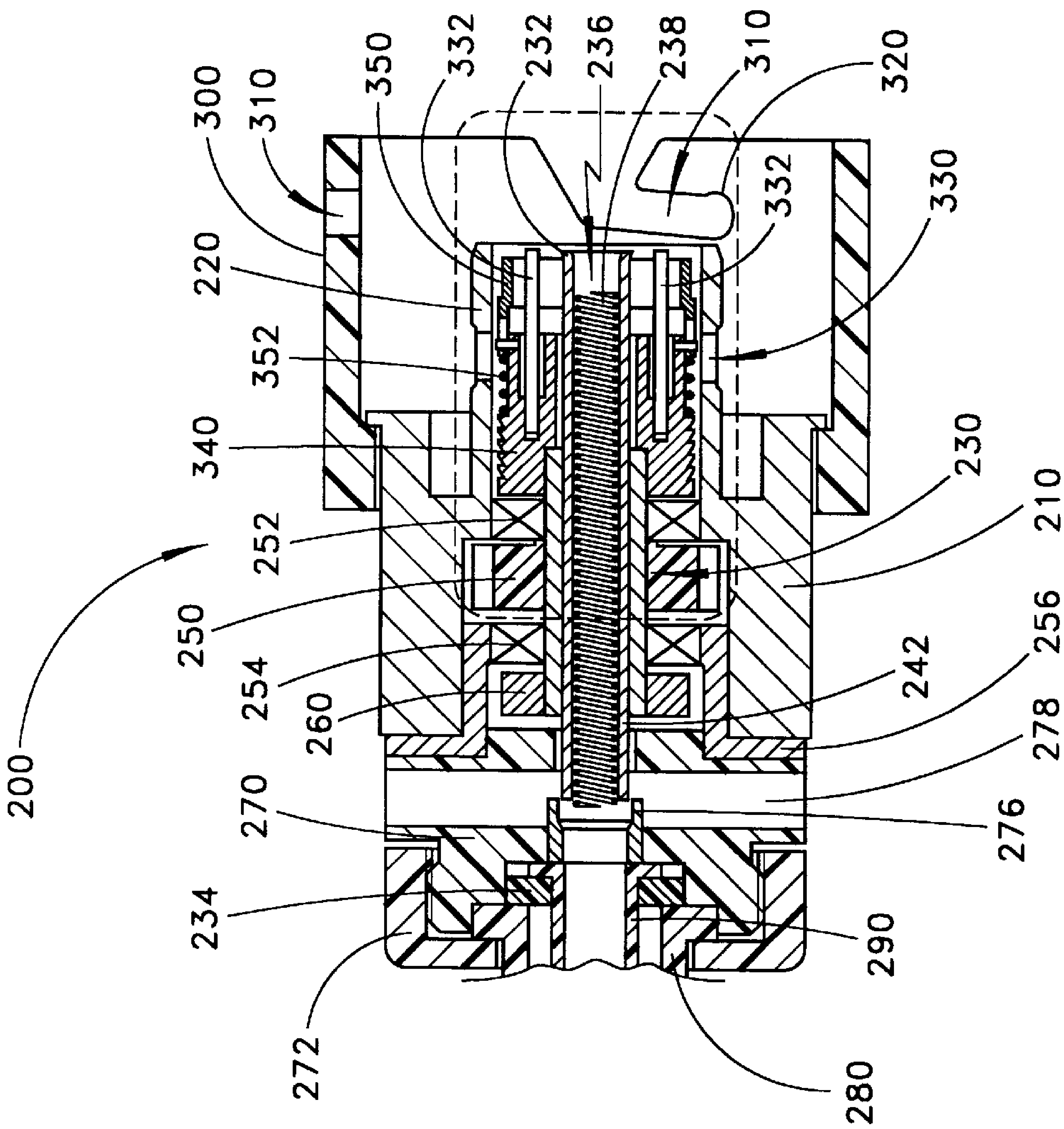
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FIG. 45

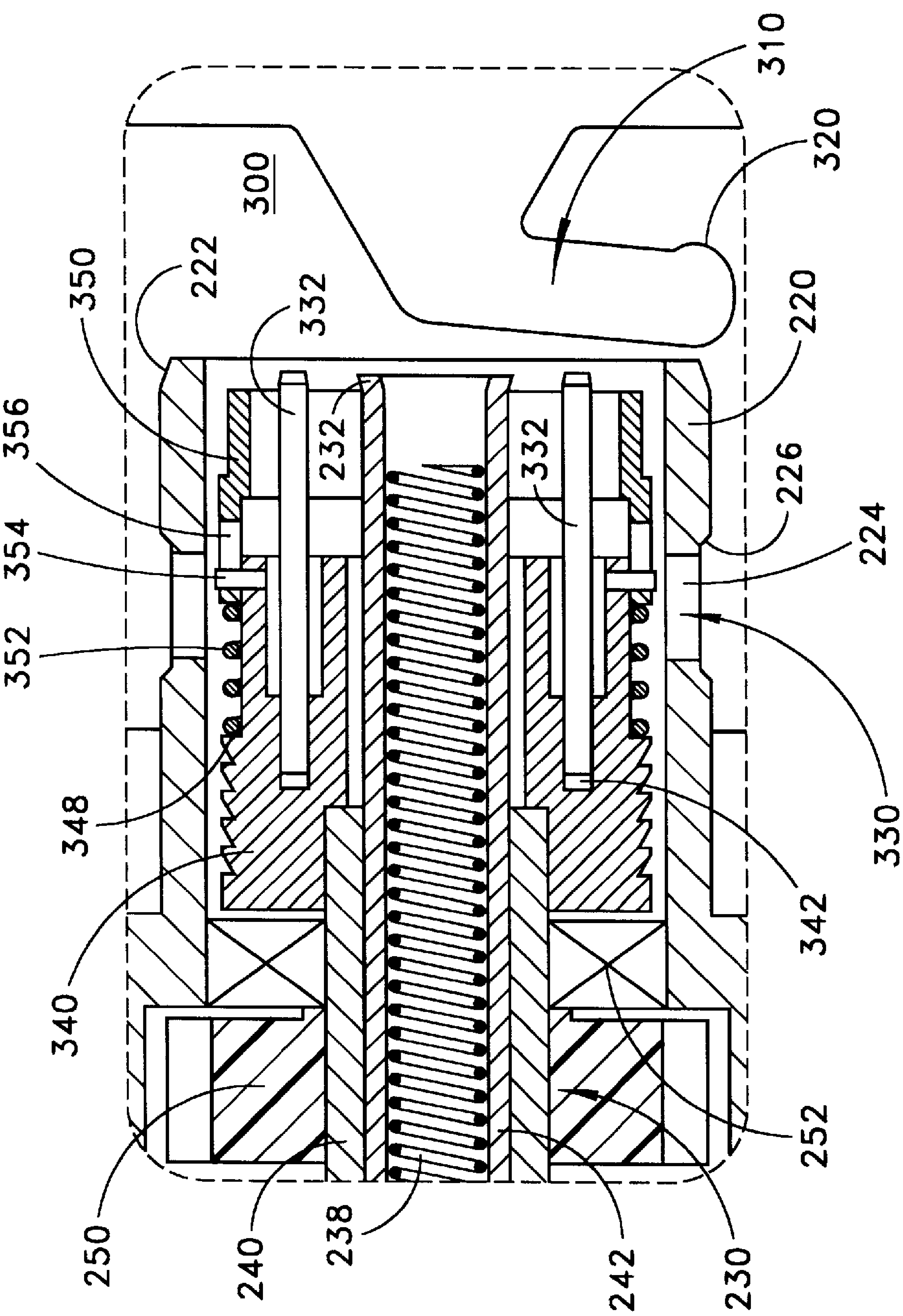
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FIG. 46

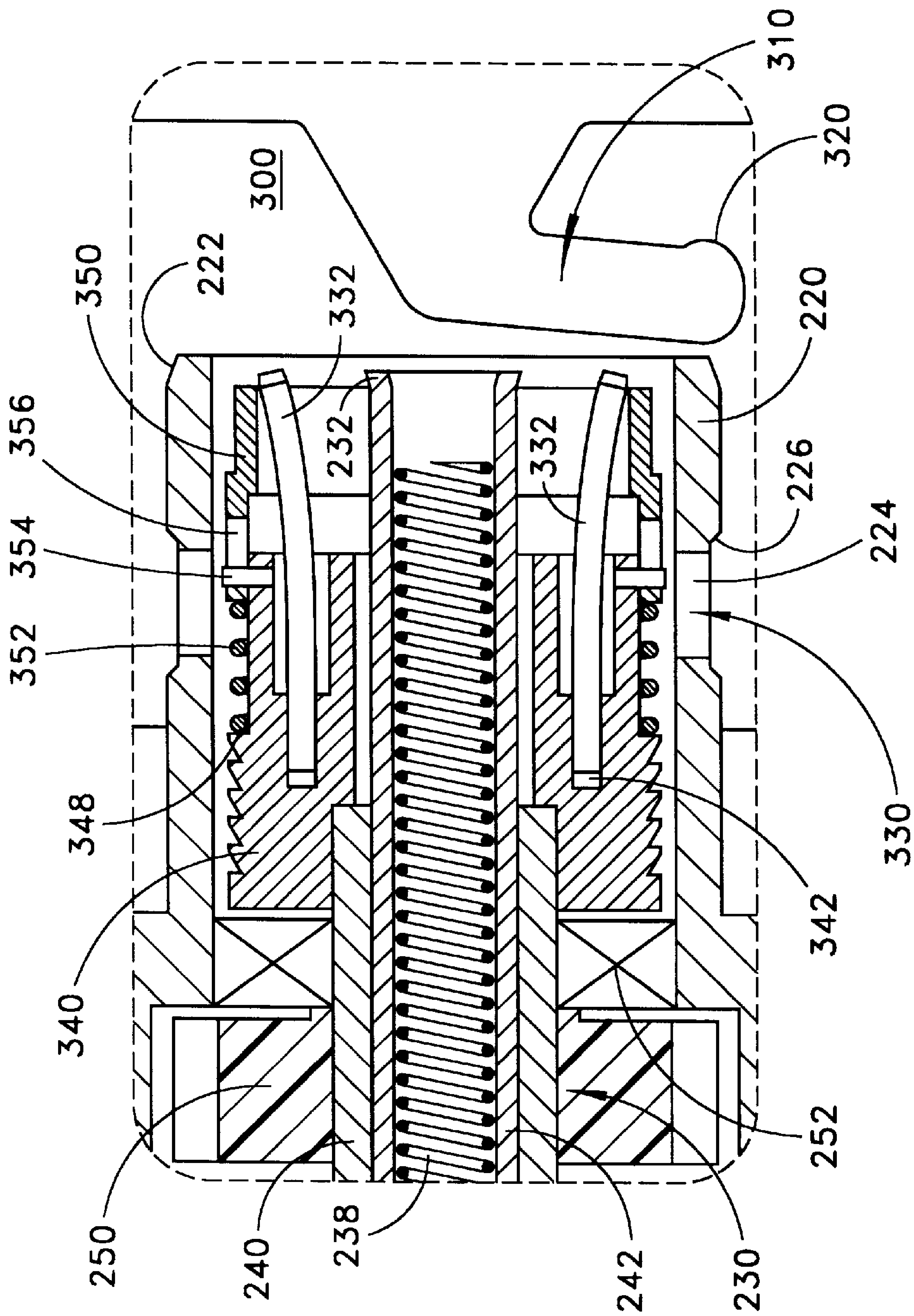
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FIG. 47

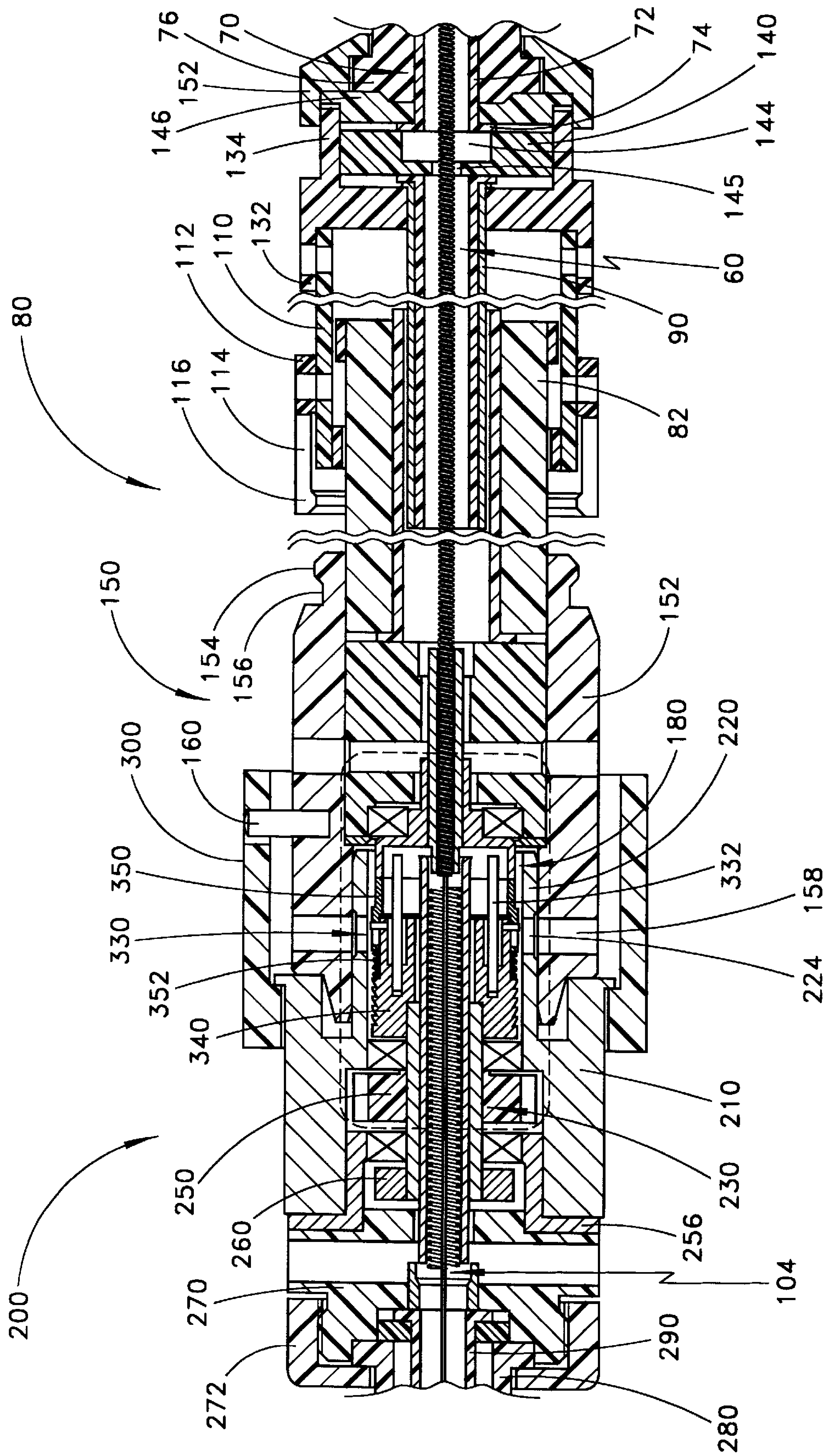
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FIG. 48

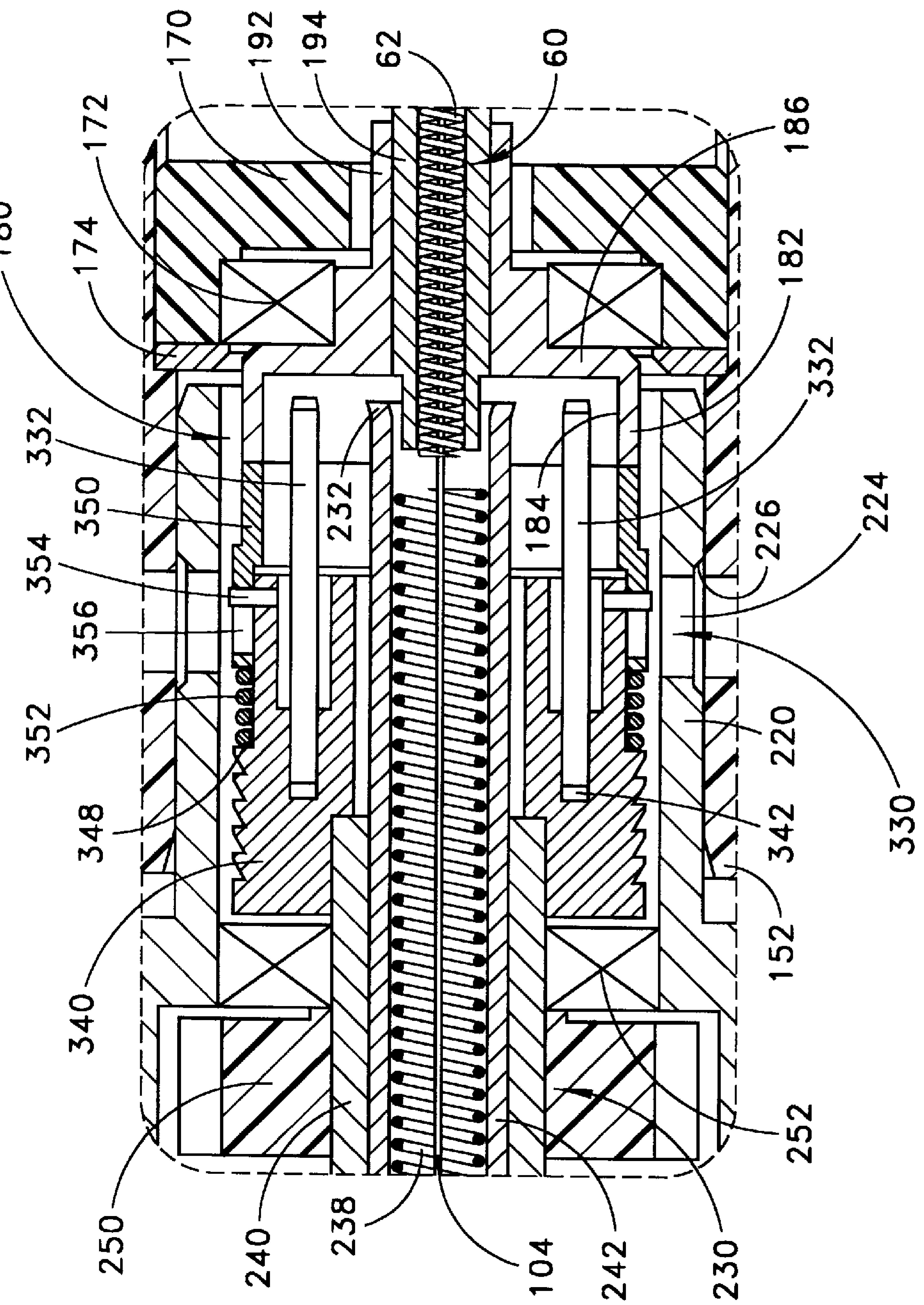
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FIG. 49

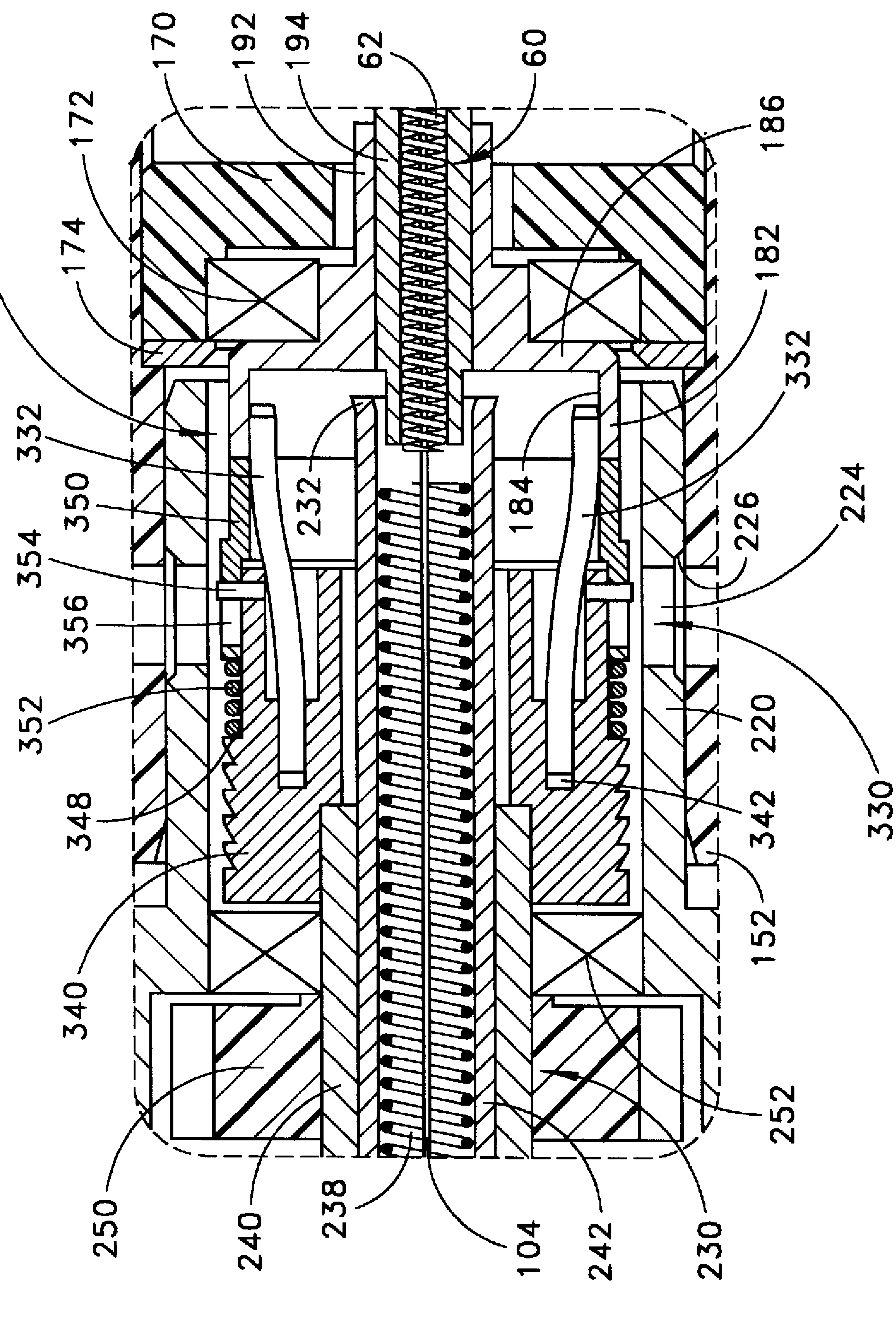
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FIG. 50

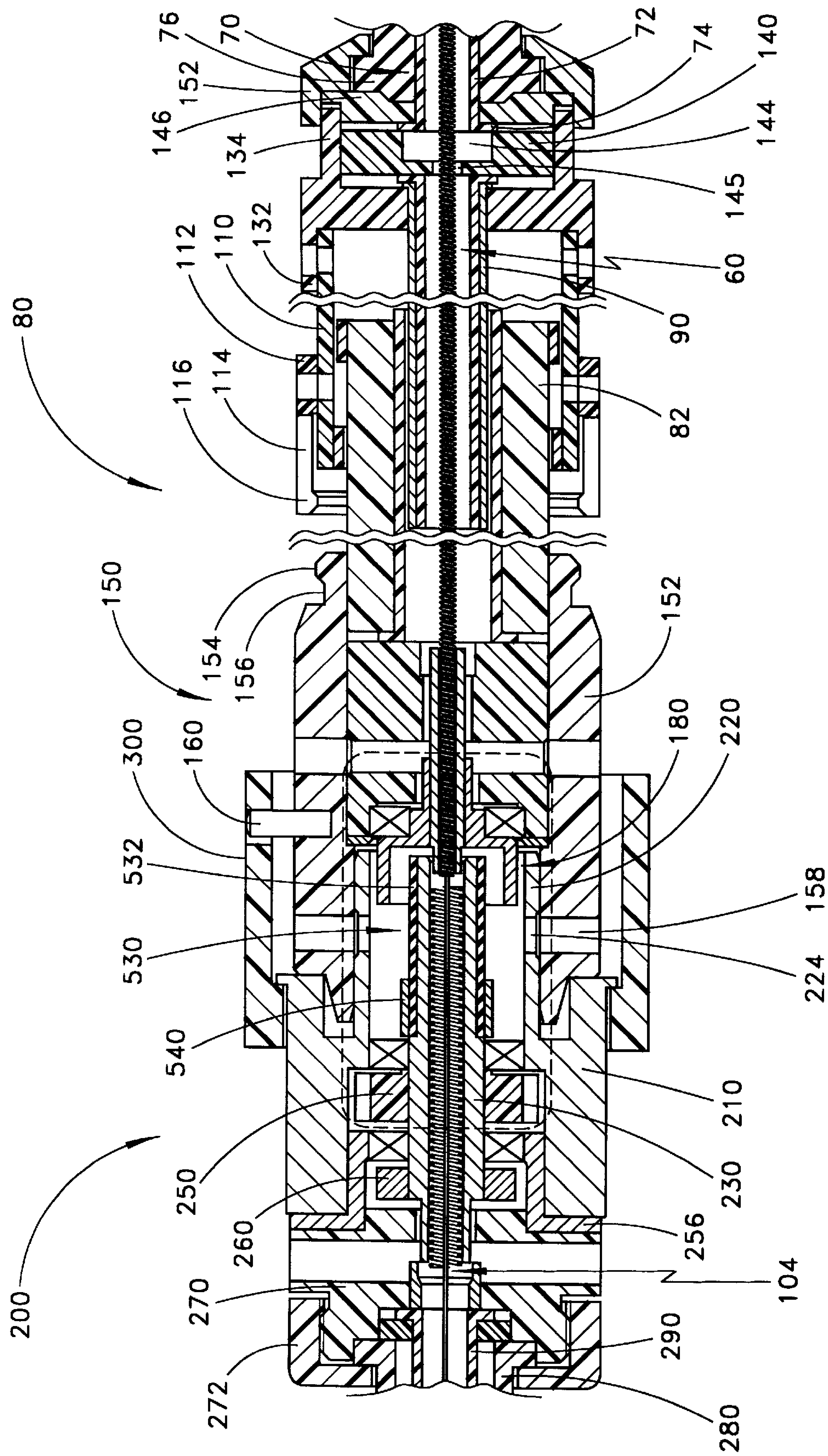
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FIG. 51

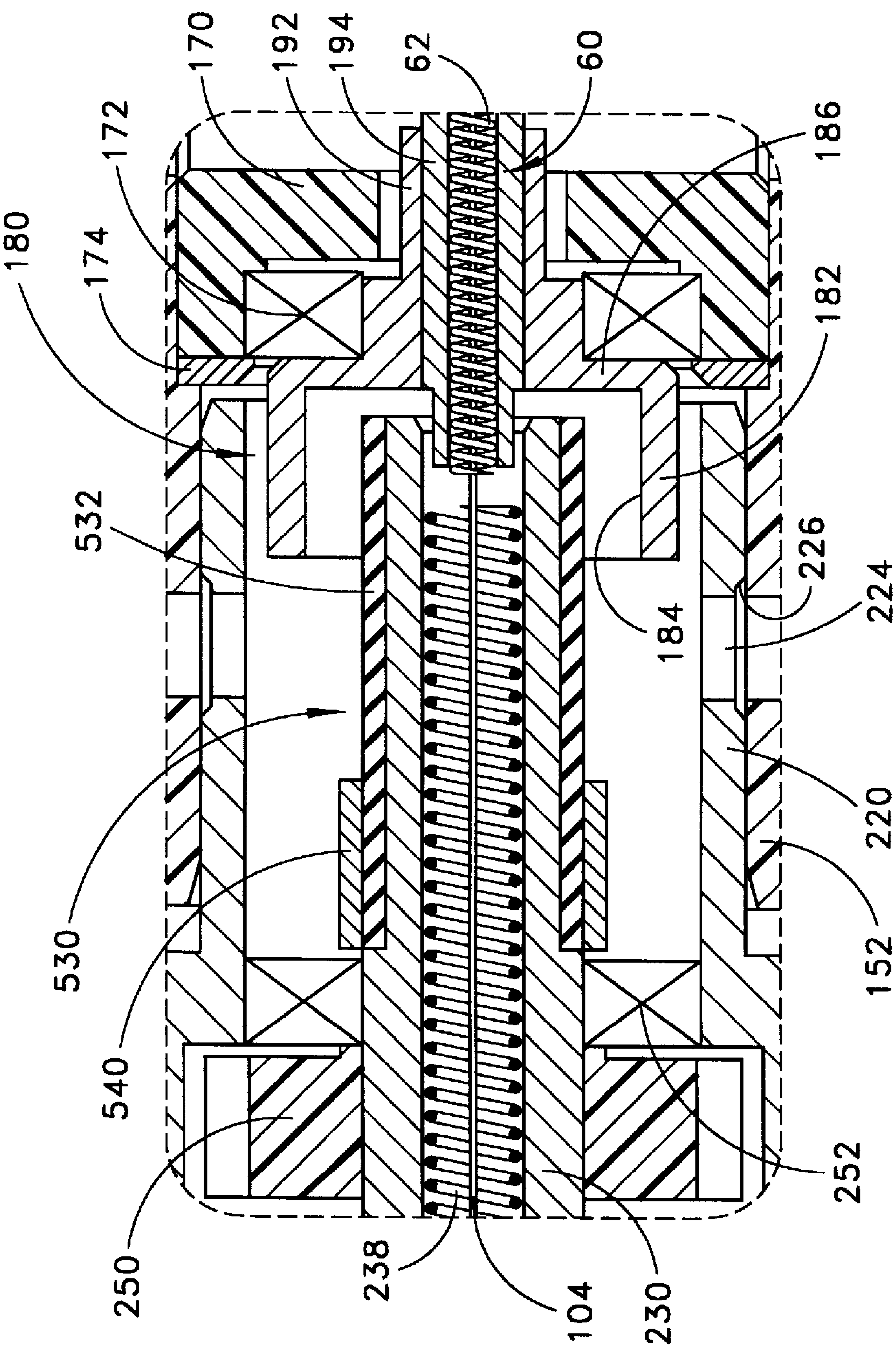
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FIG. 52

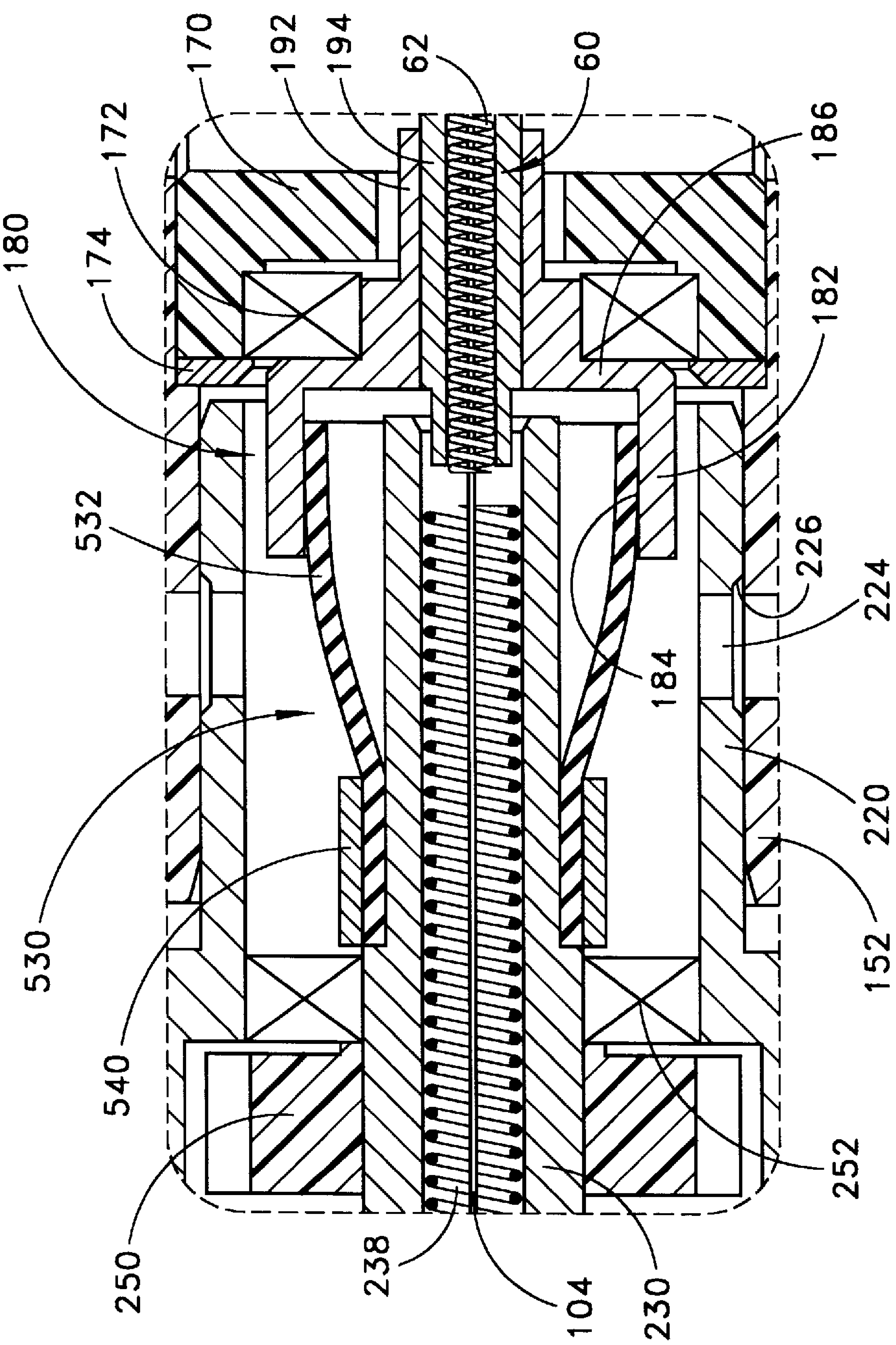
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FIG. 53

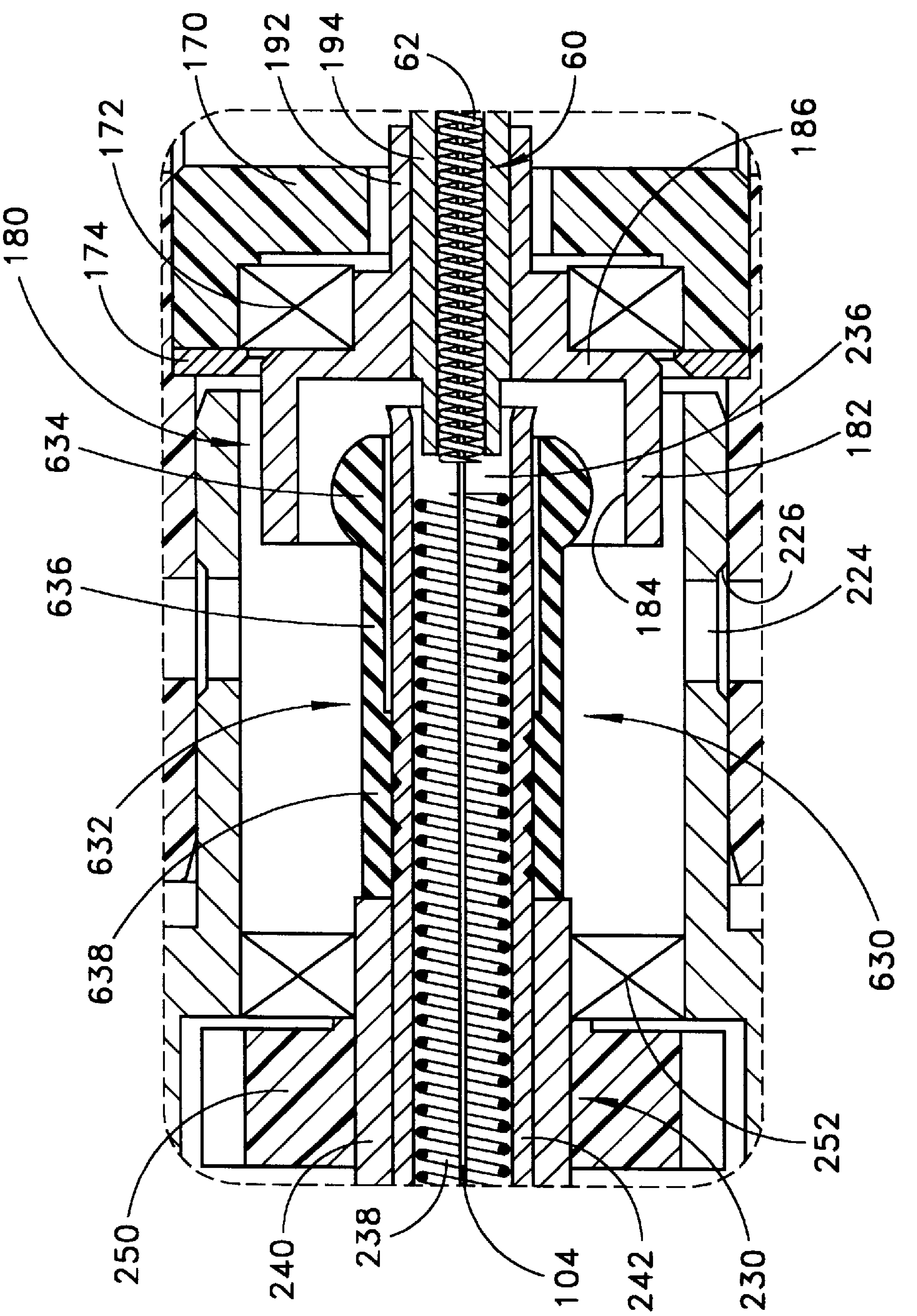
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FIG. 54

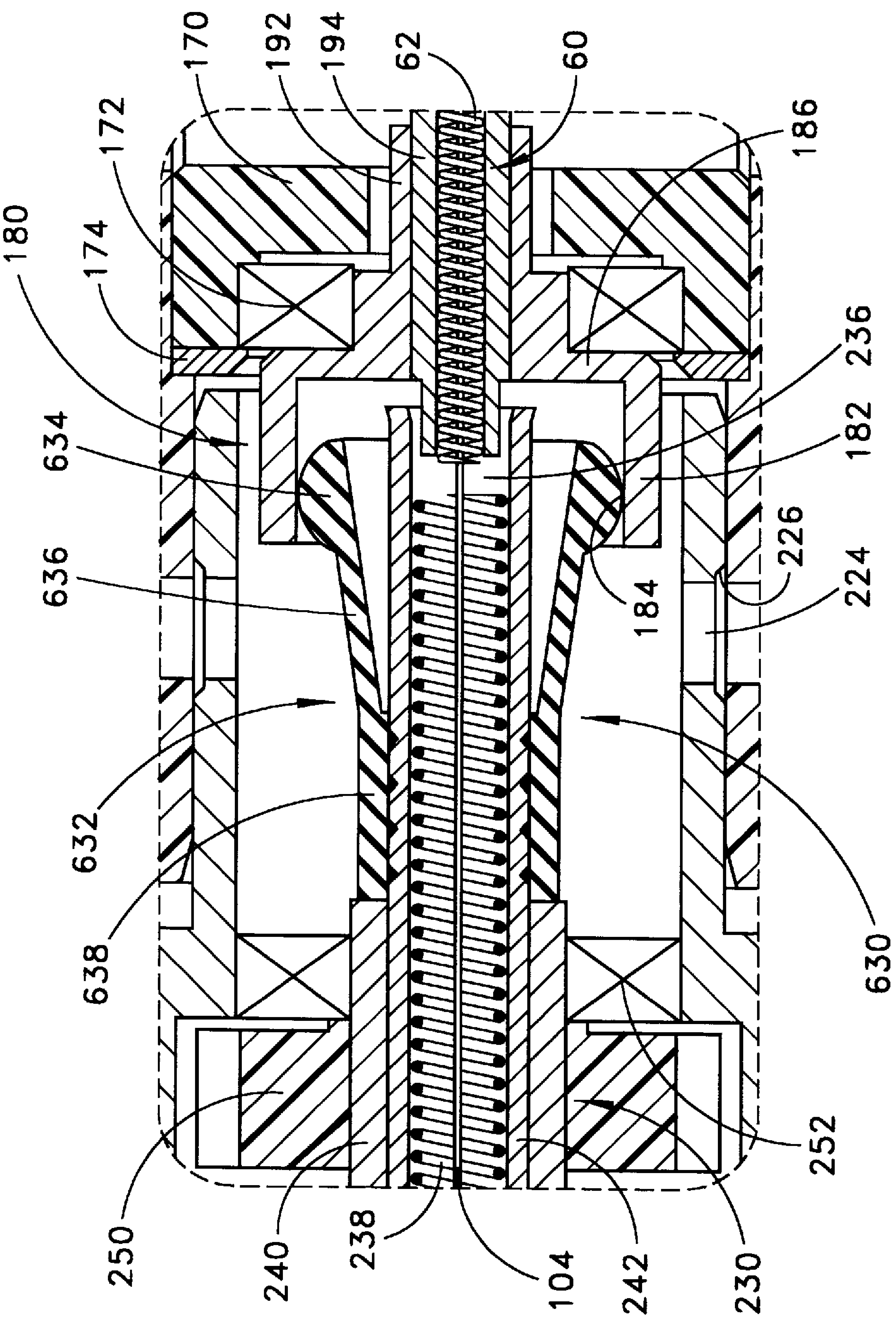
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FIG. 55

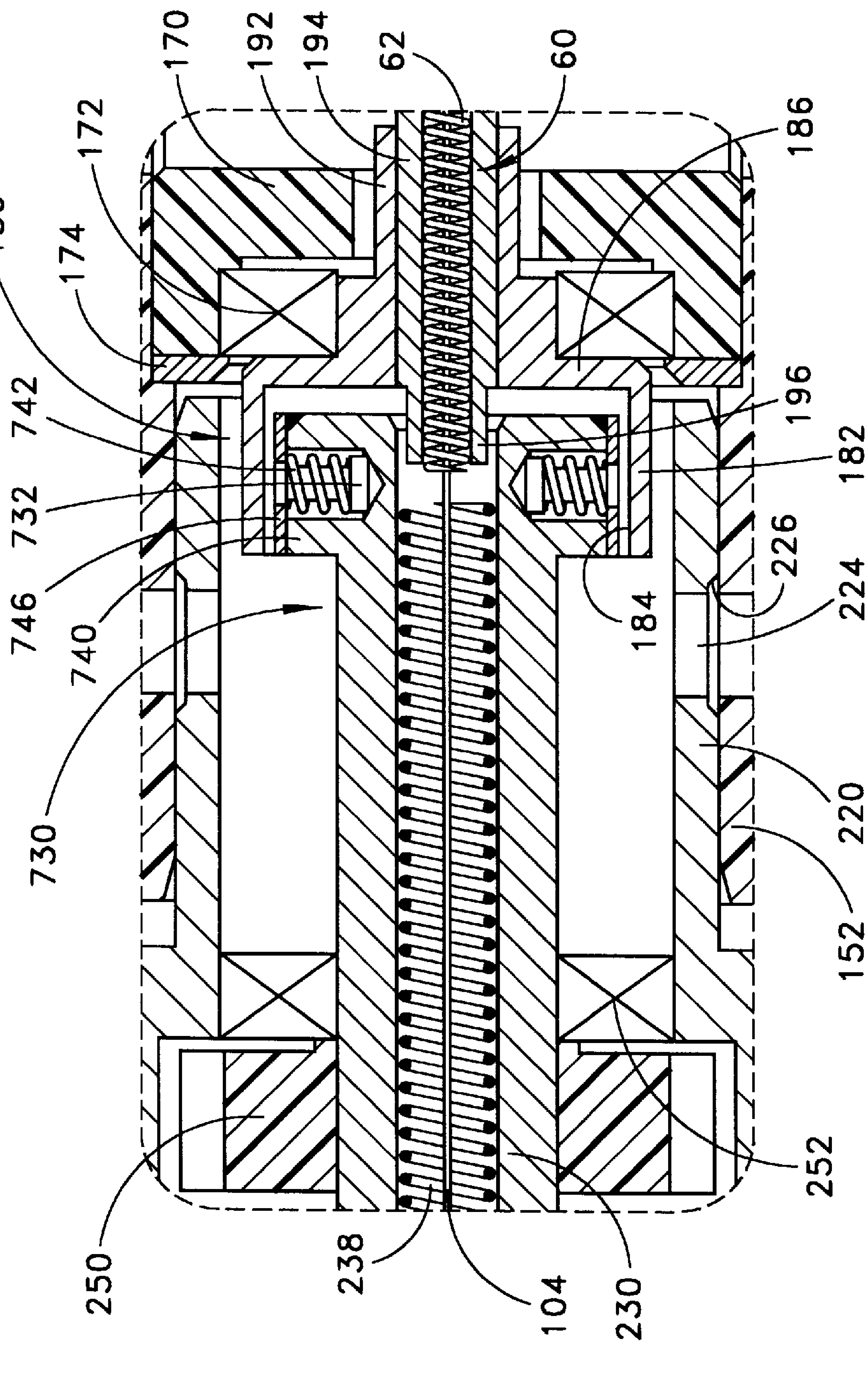
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FIG. 56

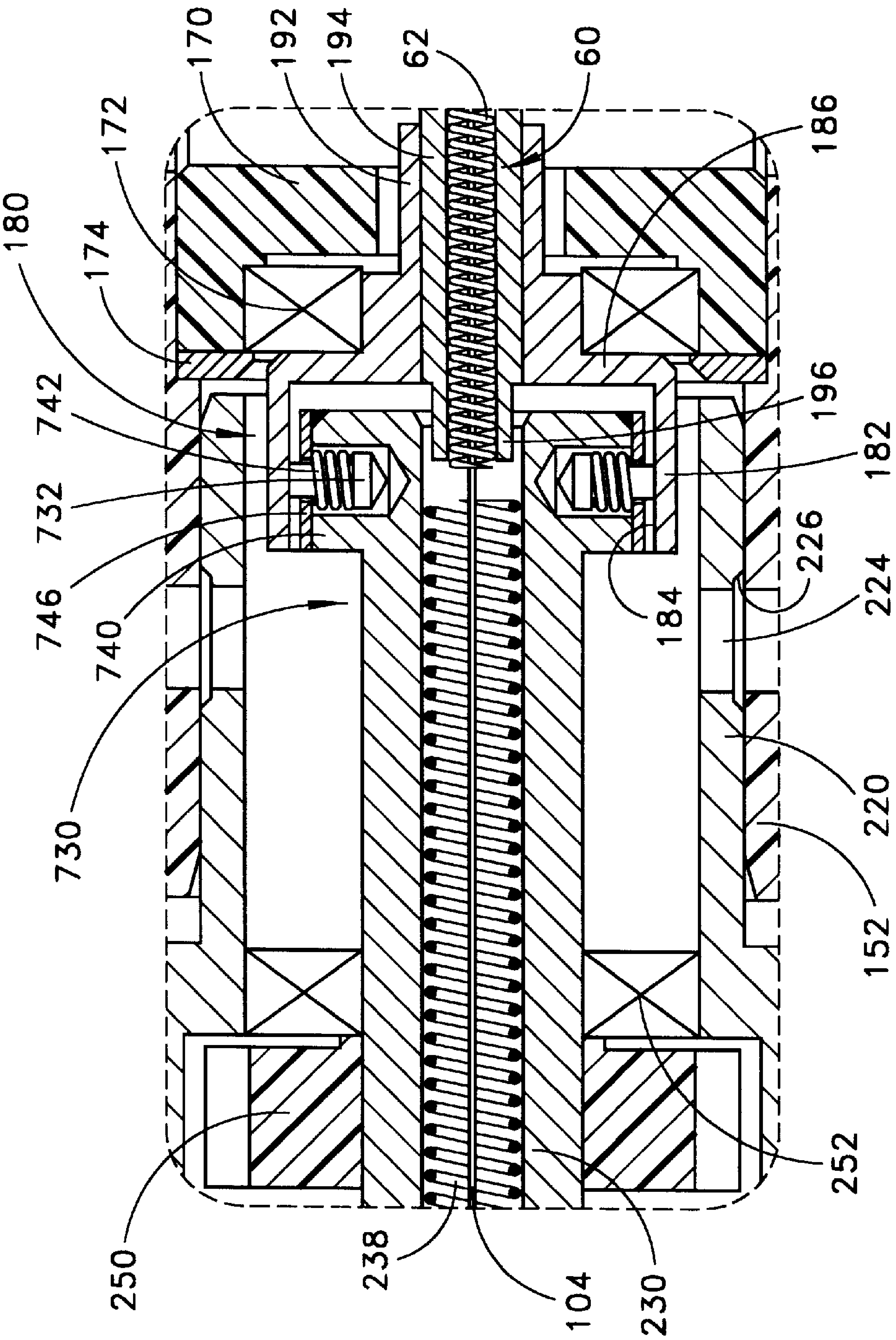
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FIG. 57

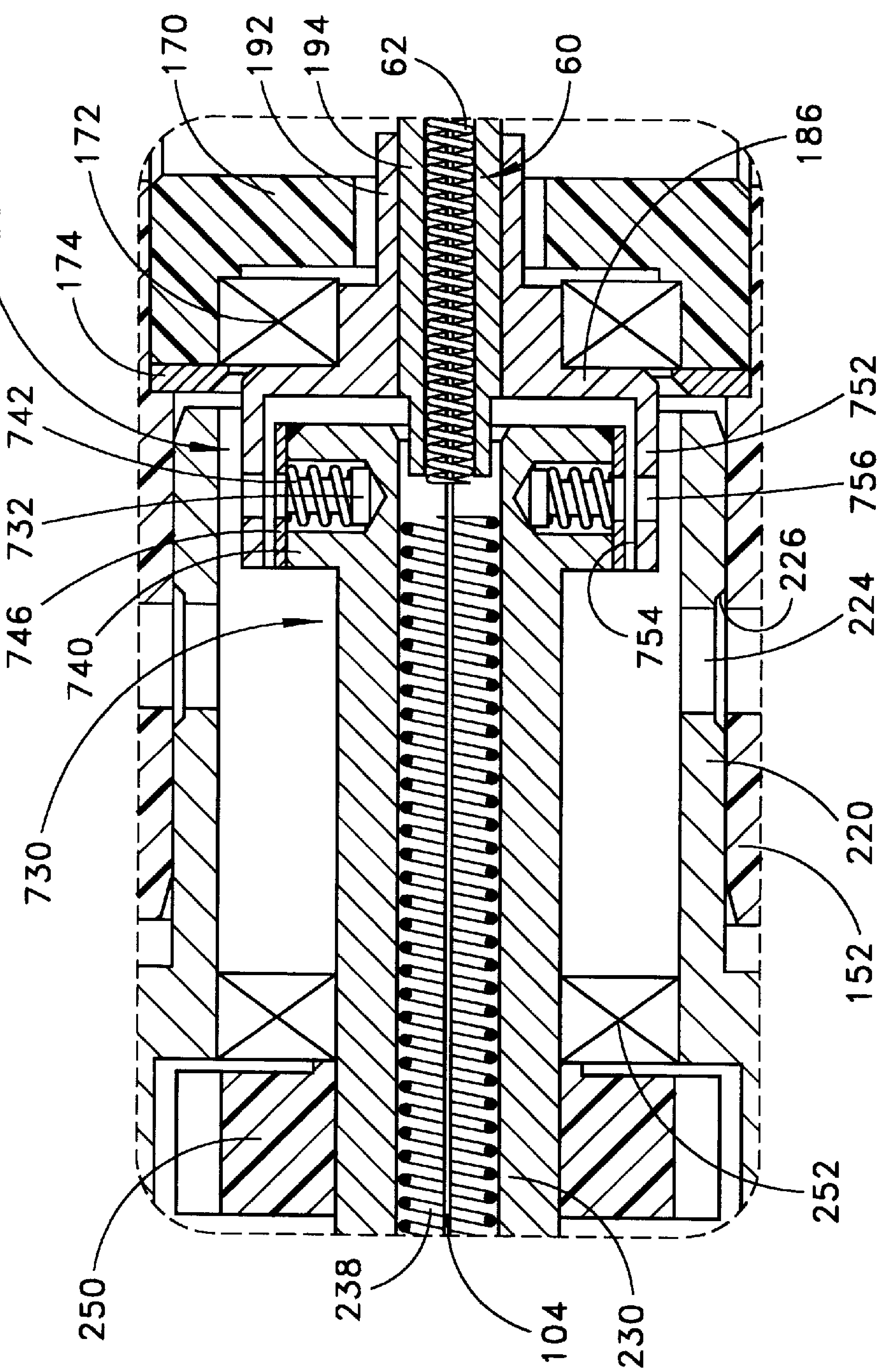
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FIG. 58

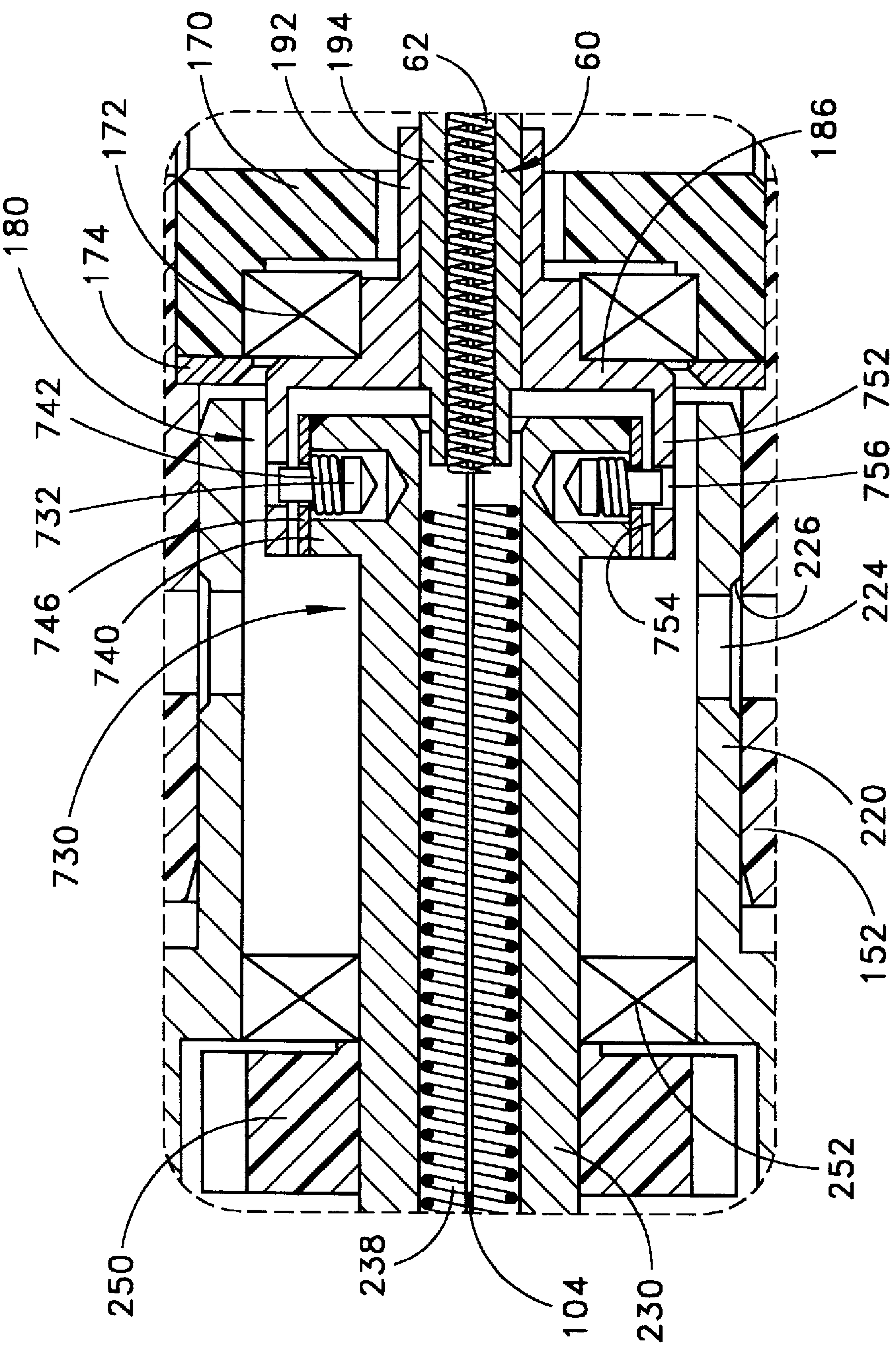
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FIG. 59

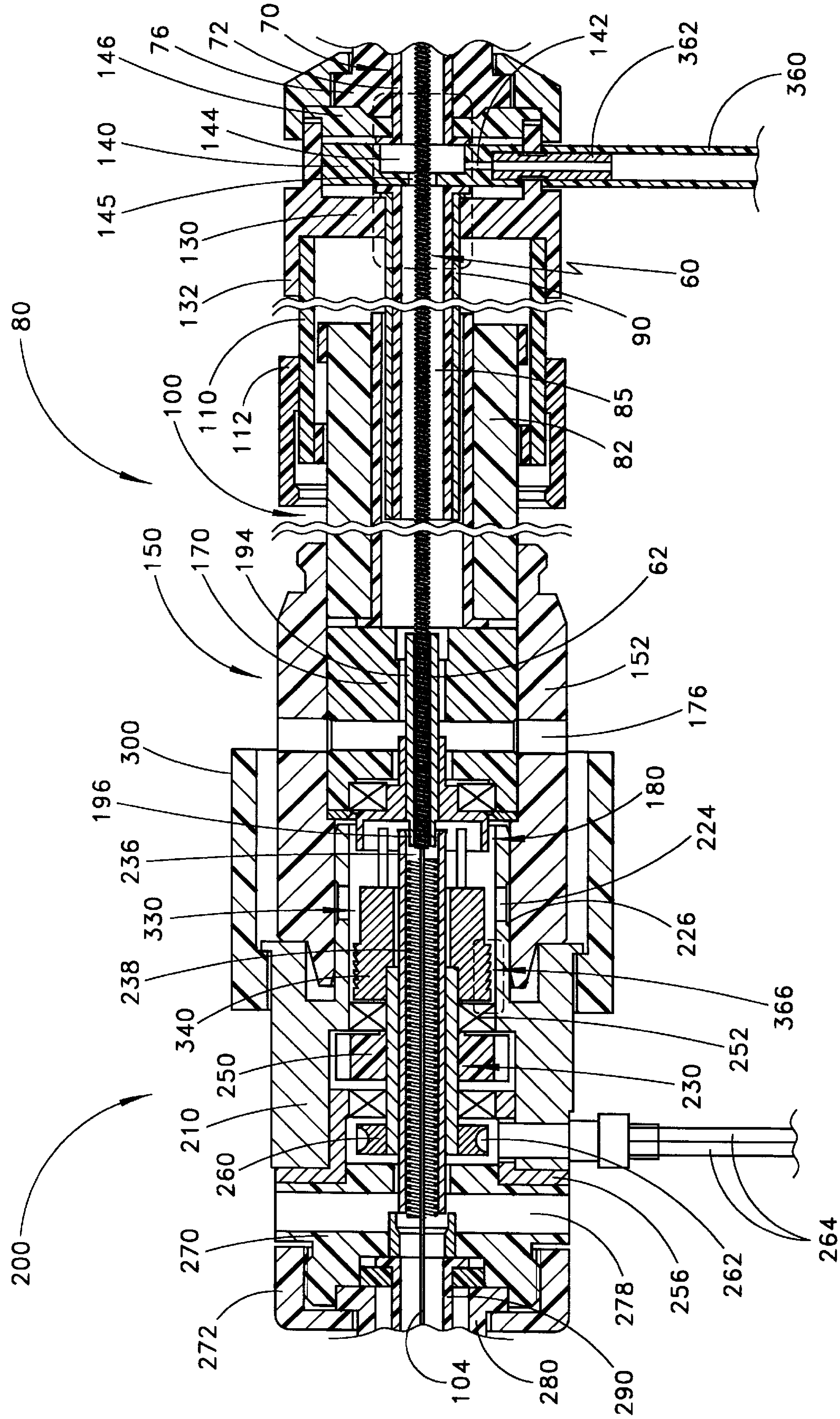
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FIG. 60

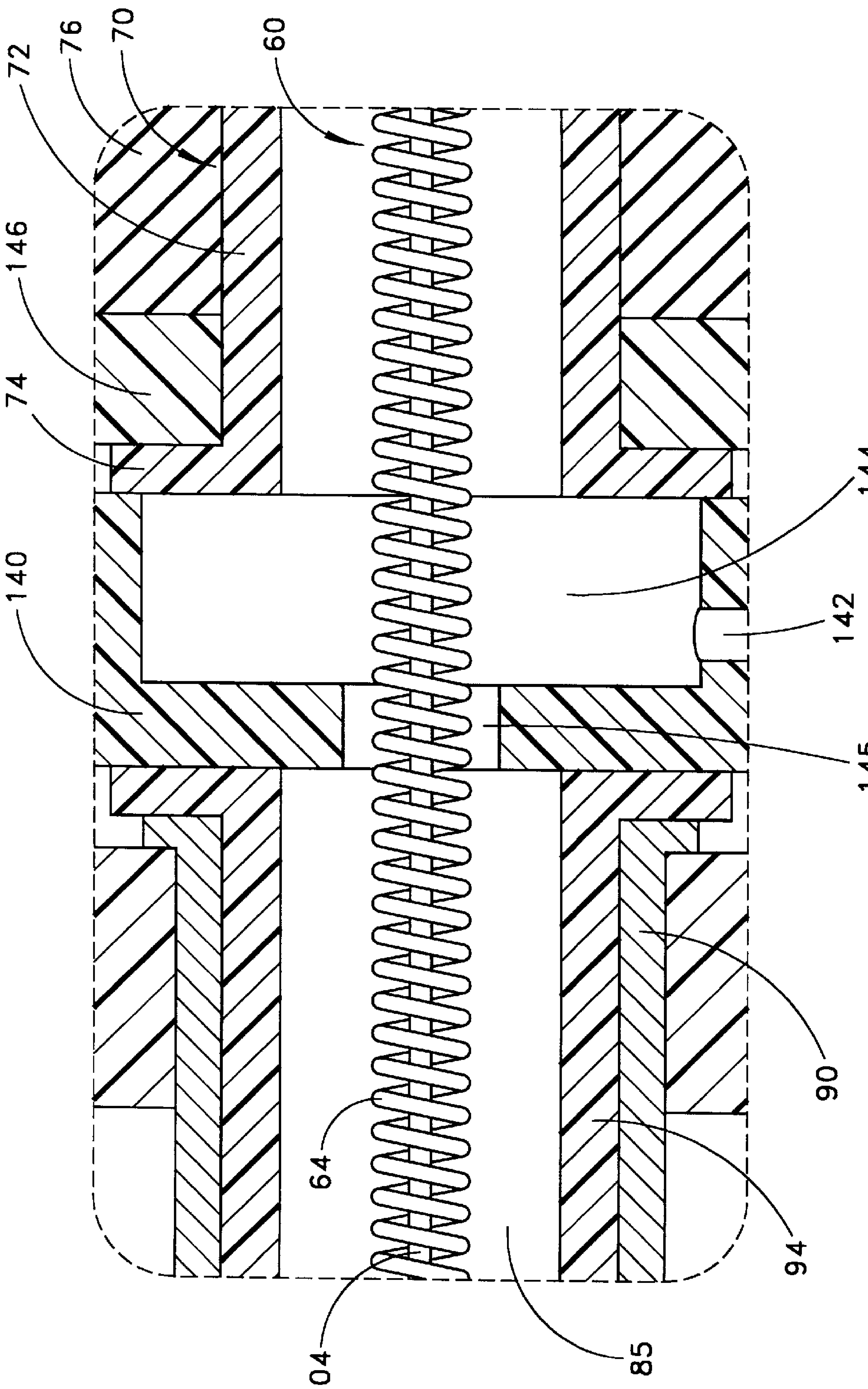

FIG. 61

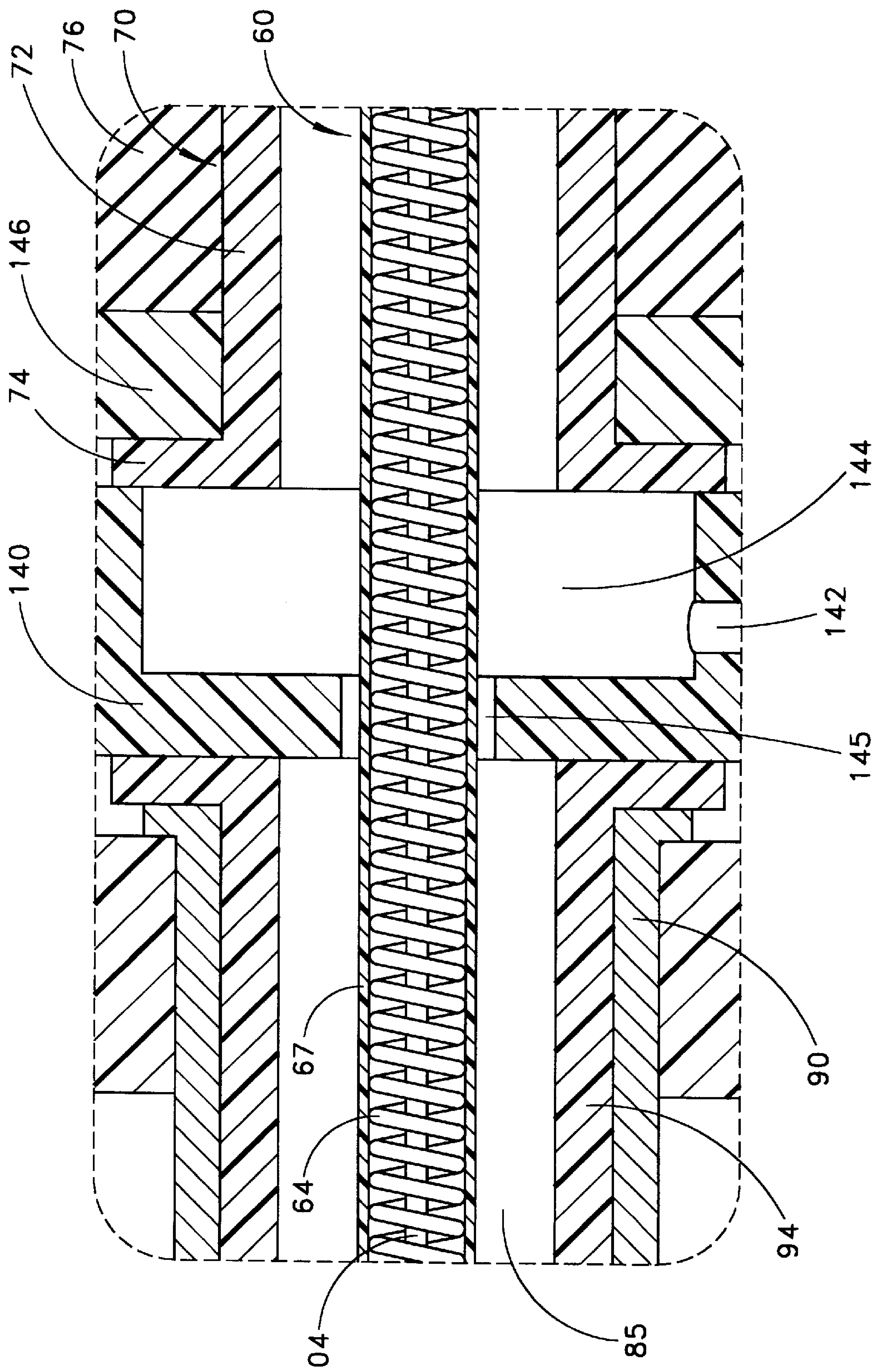

FIG. 62

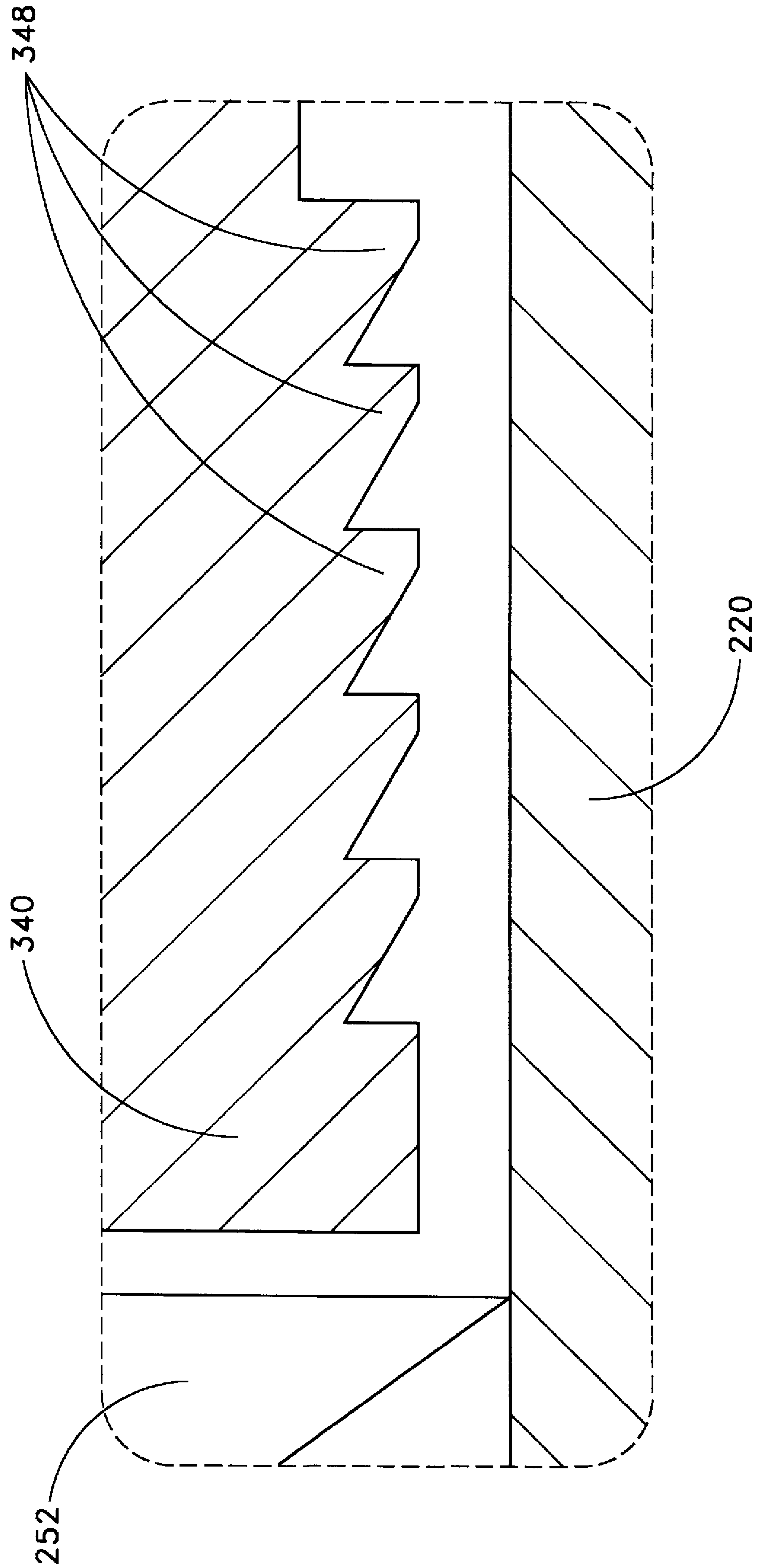

FIG. 63

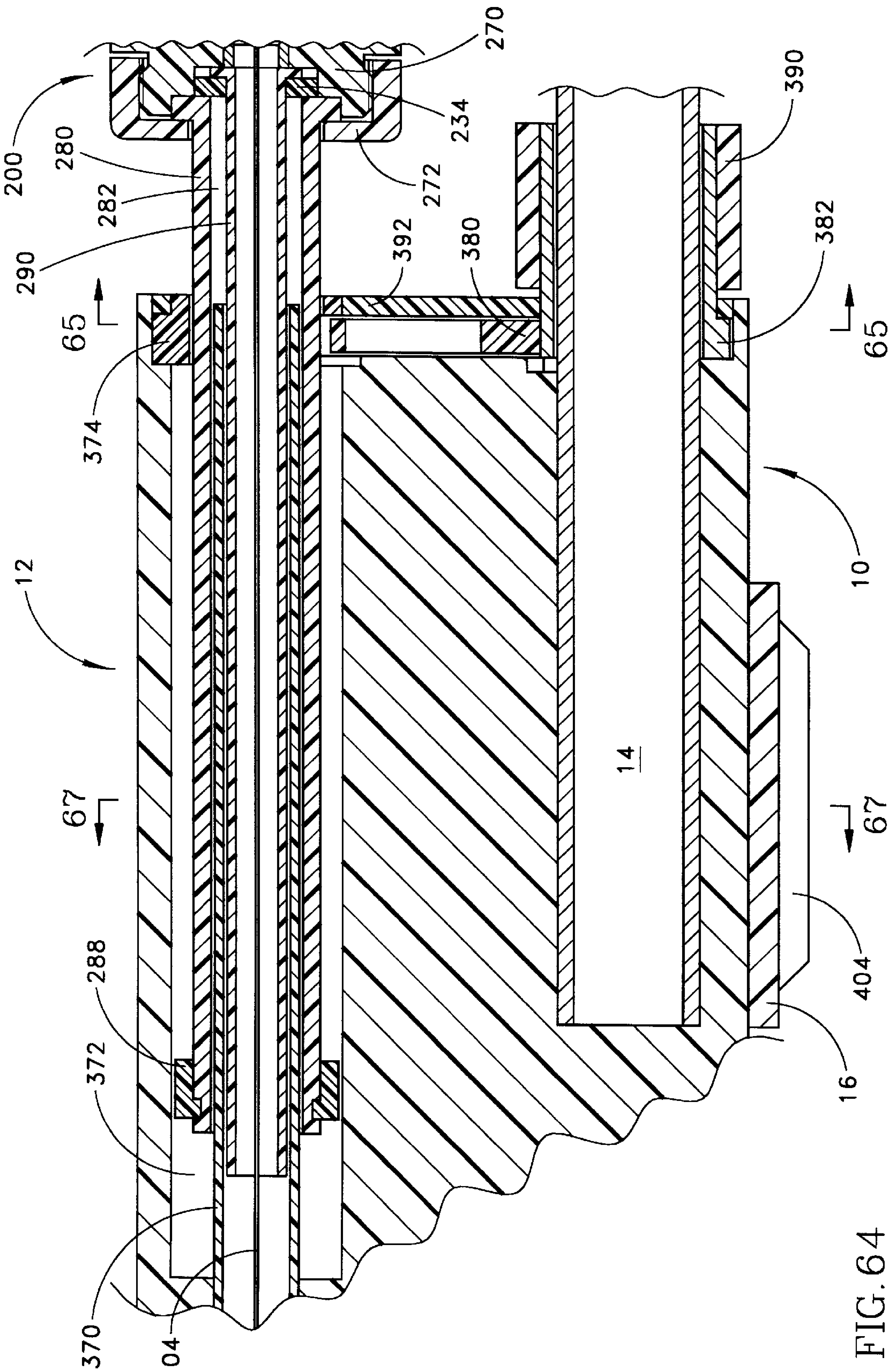
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FIG. 64

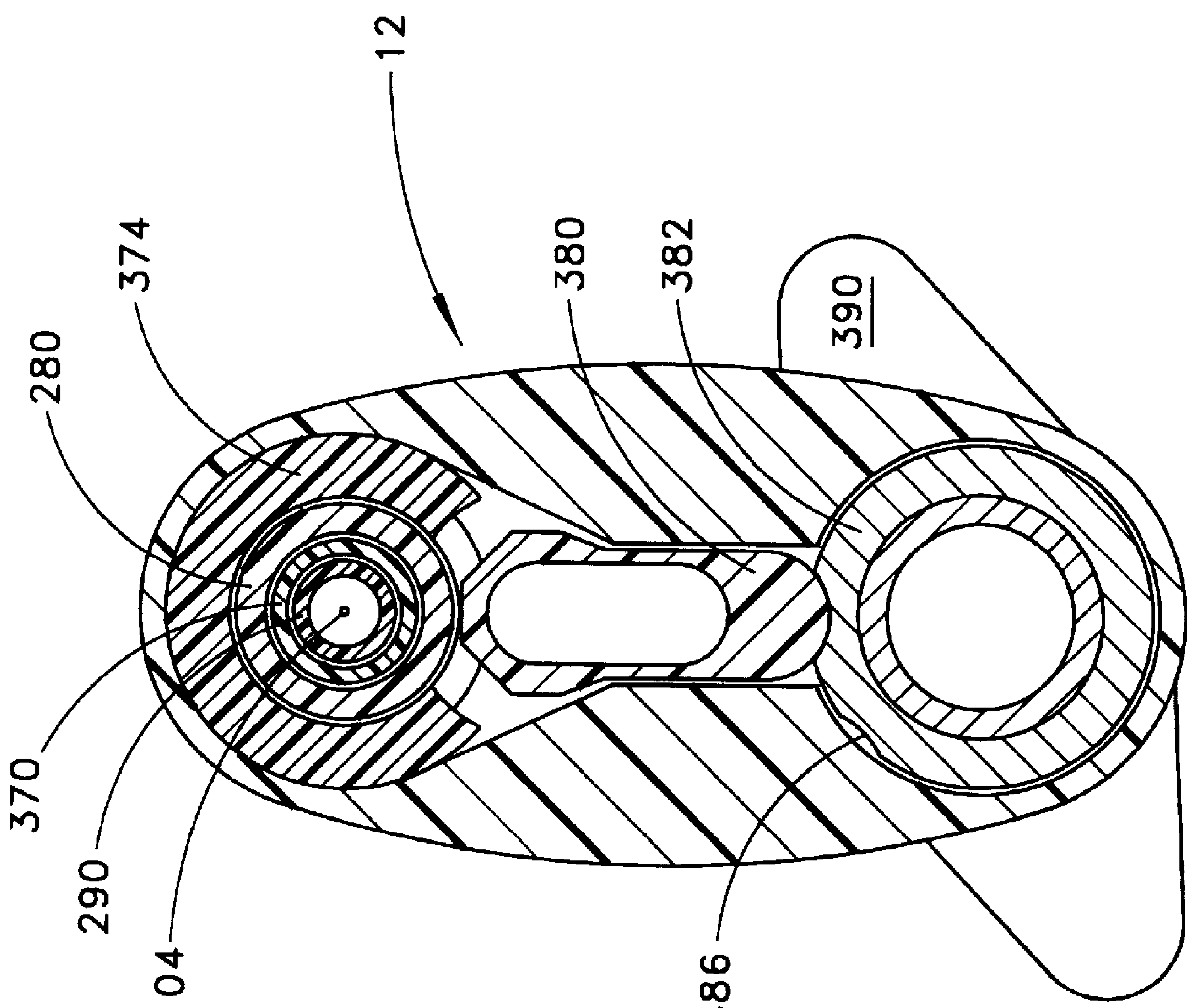

FIG. 65

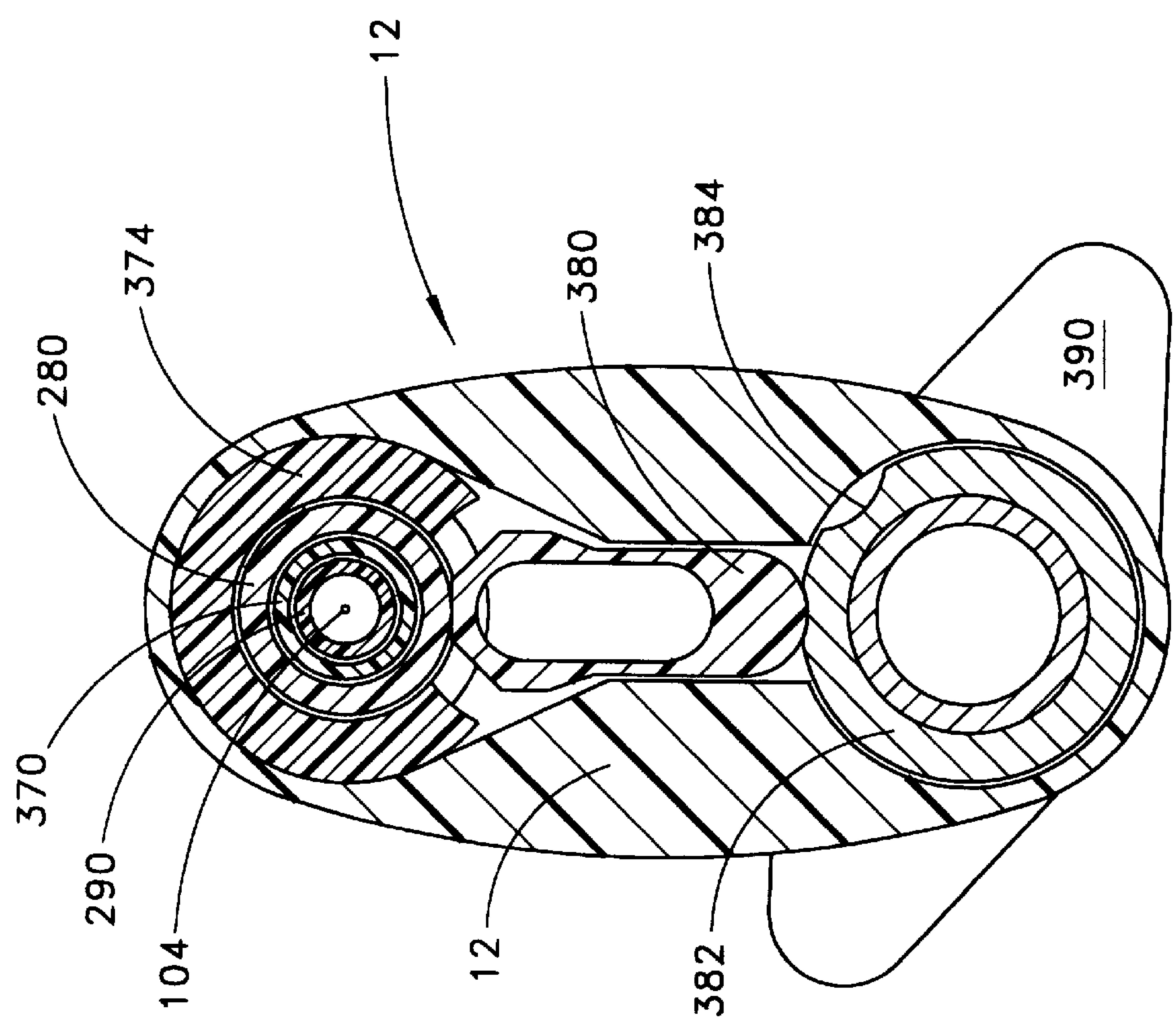

FIG. 66

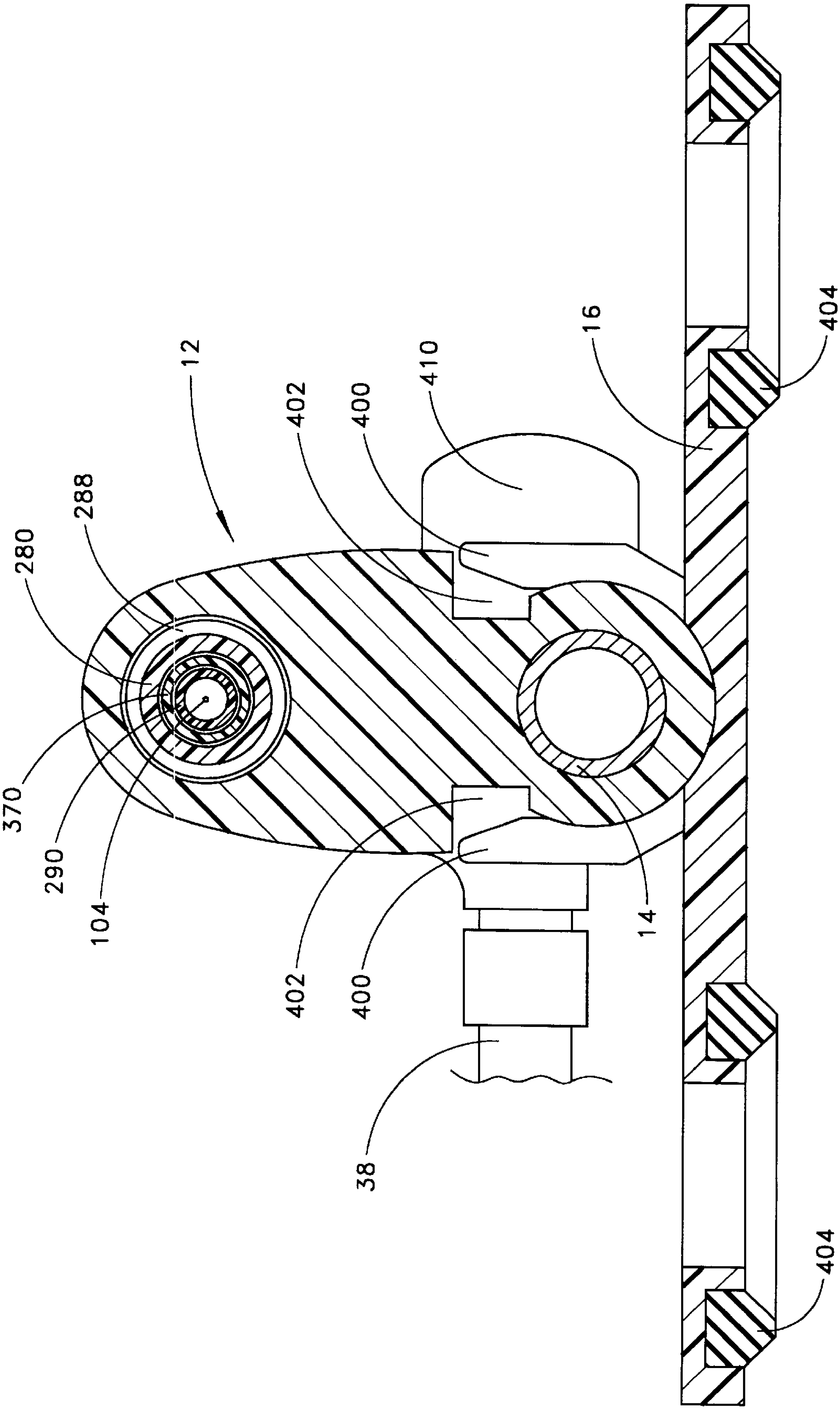

FIG. 67

ROTATIONAL ATHERECTOMY DEVICE WITH RADIALLY EXPANDABLE PRIME MOVER COUPLING

The present application is a continuation-in-part of U.S. patent application Ser. No. 08/792,101, filed 31 Jan. 1997 and now U.S. Pat. No. 5,779,722, which is, in turn, a continuation-in-part of U.S. patent application Ser. No. 08/785,991, filed 21 Jan. 1997 and now U.S. Pat. No. 5,893,857.

FIELD OF THE INVENTION

The invention relates to devices and methods for removing tissue from body passageways, such as removal of atherosclerotic plaque from arteries, utilizing a rotational atherectomy device. In particular, the invention relates to improvements in a rotational atherectomy device having an exchangeable drive shaft. This invention may also have additional uses unrelated to atherectomy devices.

BACKGROUND OF THE INVENTION

A variety of techniques and instruments have been developed for use in the removal or repair of tissue in arteries and similar body passageways. A frequent objective of such techniques and instruments is the removal of atherosclerotic plaque in a patient's arteries. Atherosclerosis is characterized by the buildup of fatty deposits (atheromas) in the intimal layer (i.e., under the endothelium) of a patient's blood vessels. Very often over time what initially is deposited as relatively soft, cholesterol-rich atheromatous material hardens into a calcified atherosclerotic plaque. Such atheromas restrict the flow of blood, and therefore often are referred to as stenotic lesions or stenoses, the blocking material being referred to as stenotic material. If left untreated, such stenoses can cause angina, hypertension, myocardial infarction, strokes and the like.

Several kinds of atherectomy devices have been developed for attempting to remove some or all of such stenotic material. In one type of device, such as that shown in U.S. Pat. No. 4,990,134 (Auth), a rotating burr covered with an abrasive cutting material, such as diamond grit (diamond particles or dust), is carried at the distal end of a flexible, rotatable drive shaft.

U.S. Pat. No. 5,314,438 (Shturman) shows another atherectomy device having a rotatable drive shaft with a section of the drive shaft having an enlarged diameter, at least a segment of this enlarged diameter section being covered with an abrasive material to define an abrasive segment of the drive shaft. When rotated at high speeds, the abrasive segment is capable of removing stenotic tissue from an artery.

U.S. Pat. No. 5,314,407 (Auth) shows details of a type of handle which may be used in conjunction with rotational atherectomy devices of the type shown in the Auth '134 and Shturman '438 patents. A handle of the type shown in the Auth '407 patent has been commercialized by Heart Technology, Inc. (Redmond, Wash.), now owned by Boston Scientific Corporation (Natick, Mass.) in the rotational atherectomy device sold under the trademark Rotablator®. The handle of the Rotablator® device includes a variety of components, including a compressed gas driven turbine, a mechanism for clamping a guide wire extending through the drive shaft, portions of a fiber optic tachometer, and a pump for pumping saline through the drive shaft.

The connection between the drive shaft (with its associated burr) and the turbine in the Rotablator® device is

permanent; yet, frequently it is necessary to use more than one size burr during an atherectomy procedure. That is, often a smaller size burr is first used to open a stenosis to a certain diameter, and then one or more larger size burrs are used to open the stenosis further. Such use of multiple burrs of subsequently larger diameter is sometimes referred to as a "step up technique" and is recommended by the manufacturer of the Rotablator® device. In the multiple burr technique it is necessary to use a new Rotablator® device for each such successive size burr. Accordingly, there is a need for an atherectomy system that would permit a physician to use only one handle throughout an entire procedure and to attach to such handle an appropriate drive shaft and tissue removing implement (e.g., a burr) to initiate the procedure and then exchange the drive shaft and the tissue removing implement for a drive shaft having a tissue removing implement of a different size or even a different design.

A subsequent version of the Rotablator® has been introduced with the ability to exchange a flexible distal portion of the drive shaft together with a burr for another distal portion of a drive shaft having a different size burr. Technical details of such a system are contained in international patent application No. WO 96/37153. This system utilizes a flexible drive shaft having a connect/disconnect feature allowing the physician to disconnect the exchangeable distal portion of the flexible drive shaft together with the burr from the flexible proximal portion of the drive shaft which is connected to the turbine of the handle, thus permitting the burr size to be changed without discarding the entire atherectomy unit. Each exchangeable drive shaft portion is disposed within its own exchangeable catheter and catheter housing. The flexible proximal portion of the drive shaft in this system is permanently attached to the turbine and is not exchanged. This system has been commercialized by Boston Scientific under the trademark Rotalink System™. While the Rotalink System™ does permit one to change the burr size, the steps required to actually disconnect the exchangeable portion of the drive shaft and replace it with another exchangeable portion of the drive shaft are quite involved and require relatively intricate manipulation of very small components.

First, a catheter housing must be disconnected from the handle and moved distally away from the handle to expose portions of both the proximal and distal sections of the flexible drive shaft which contain a disconnectable coupling. This coupling is disconnected by sliding a lock tube distally, permitting complementary lock teeth on the proximal and distal portions of the flexible drive shaft to be disengaged from each other. A similar flexible distal drive shaft portion with a different burr may then be connected to the flexible proximal portion of the drive shaft. To accomplish such assembly, the lock tooth on the proximal end of the distal replacement portion of the drive shaft must first be both longitudinally and rotationally aligned with the complementary lock tooth at the distal end of the proximal portion of the drive shaft. Since the flexible drive shaft typically is less than 1 mm in diameter, the lock teeth are similarly quite small in size, requiring not insignificant manual dexterity and visual acuity to properly align and interlock the lock teeth. Once the lock teeth have been properly interlocked with each other, the lock tube (also having a very small diameter) is slid proximally to secure the coupling. The catheter housing must then be connected to the handle housing.

While this system does permit one to exchange one size burr (together with a portion of the drive shaft) for a burr of another size, the exchange procedure is not an easy one and must be performed with considerable care. The individual performing the exchange procedure must do so while wearing surgical gloves to protect the individual from the blood of the patient and to maintain the sterility of the elements of the system. Surgical gloves diminish the tactile sensations of the individual performing the exchange procedure and therefore make such exchange procedure even more difficult.

Accordingly, it would be desirable to have an atherectomy device permitting easier attachment and/or exchange of the drive shaft and its tissue removing implement.

SUMMARY OF THE INVENTION

One embodiment of the present invention provides a rotational atherectomy device which includes an exchangeable drive shaft cartridge and a rotatable, radially expandable prime mover coupling. The exchangeable drive shaft cartridge desirably includes a rotatable drive shaft socket carried by a drive shaft carriage; a longitudinally extendable tube extending distally from the drive shaft carriage; an elongated catheter having a proximal end portion which is operatively connected to and may be generally aligned with a distal end portion of the longitudinally extendable tube; and a rotatable flexible drive shaft. The flexible drive shaft has proximal, intermediate and distal portions, the proximal portion being attached to the drive shaft socket, the intermediate portion being disposed primarily within the longitudinally extendable tube and the catheter, and the distal portion extending distally from the catheter and having a tissue removal implement. The prime mover coupling desirably is carried by a prime mover carriage and is connected to a prime mover for rotation therewith.

The drive shaft socket of this embodiment of the invention is sized to receive a length of the prime mover coupling therein such that the prime mover coupling does not effectively engage an interior surface of the drive shaft socket when the coupling is not rotating. However, the prime mover coupling radially expands to effectively engage the socket upon sufficiently rapid rotation of the prime mover, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover.

As a result, when the prime mover is not rotating, the drive shaft is disconnected from the prime mover, thereby permitting the exchangeable drive shaft cartridge to be replaced by another exchangeable drive shaft cartridge. Although this design permits replacement of the exchangeable drive shaft cartridge, it should be recognized that a user may choose not to actually replace one exchangeable drive shaft cartridge with another during a single procedure, e.g. where a single tissue removal implement achieves the clinical objective.

In one preferred embodiment, the prime mover coupling includes a coupling base and at least two flexible pins, each pin being anchored adjacent one end thereof to the coupling base and having another end which is free to deflect radially outwardly to engage the drive shaft socket when the prime mover is rotated. These flexible pins may be adapted to deflect radially outwardly into frictional engagement with the interior engagement surface of the drive shaft socket in response to rotation of the prime mover.

In a preferred embodiment, the drive shaft carriage and the prime mover carriage are longitudinally moveable with respect to one another from an operational position wherein a length of the prime mover coupling is received within the drive shaft socket to a non-operational position wherein the prime mover coupling is withdrawn from the drive shaft socket. In the operational position, the drive shaft carriage and the prime mover carriage can be interconnected to move together as a unit to move the drive shaft and its tissue removal implement along a vascular lumen of a patient's body.

In a further embodiment, the rotational atherectomy device includes a handle which carries the prime mover carriage and which is adapted to releasably hold the drive shaft cartridge. The handle may comprise a distal portion adapted to releasably hold the drive shaft cartridge, a proximal portion carrying the prime mover carriage, and an elongated rod connecting the distal and proximal portions of the handle to one another.

A preferred embodiment includes a flexible fluid supply tubing attached to the exchangeable drive shaft cartridge. The flexible fluid supply tubing may be in fluid communication with a drive shaft lumen of the drive shaft cartridge, the drive shaft lumen being defined by a lumen of the catheter and a lumen of the longitudinally extendable tube. Optimally, the drive shaft lumen includes a reduced inner diameter segment, the reduced inner diameter segment being positioned proximally of where the fluid supply tubing delivers fluid to the drive shaft lumen, thereby reducing flow of fluid proximally along the drive shaft lumen.

In yet another embodiment, the prime mover carriage carries a coupling shield which restricts radial expansion of the prime mover coupling upon rotation of the prime mover when the prime mover coupling is not properly received within the drive shaft socket. This coupling shield may be carried by the prime mover coupling and can be moved away from a distal end of the coupling to permit the coupling to be properly received within the drive shaft socket so the coupling can engage the socket upon rotation of the prime mover.

An alternative embodiment of the invention provides a simplified system for releasably connecting a drive shaft to a prime mover. This system also includes an exchangeable drive shaft cartridge and a rotatable, radially expandable prime mover coupling. This embodiment of the invention may provide a more cost-efficient approach in connection with medical devices and may be used successfully in fields unrelated to medical devices. The exchangeable drive shaft cartridge desirably includes rotatable drive shaft socket carried by a drive shaft carriage and a rotatable drive shaft having a proximal portion attached to the drive shaft socket. The prime mover coupling is connected to a prime mover for rotation therewith, the prime mover coupling comprising a coupling base and at least two flexible pins, each pin being anchored adjacent one end thereof to the coupling base and having another end which is free to deflect radially outwardly to engage the drive shaft socket when the prime mover is rotated. The drive shaft socket of this embodiment is sized to receive the free end portions of the pins of the prime mover coupling therein such that the pins do not contact the interior surface of the drive shaft socket when the coupling is not rotating, but the free end portions of the pins deflect into frictional engagement with the socket upon sufficiently rapid rotation of the prime mover, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover. As a result, when the prime mover is not rotating, the drive shaft is disconnected from the prime mover, thereby permitting the exchangeable drive shaft cartridge to be replaced by another exchangeable drive shaft cartridge, if so desired.

The present invention also contemplates a method of removing tissue from passageways in a human body or removing a variety of materials from various cavities or passageways. This method may be used in a variety of industrial applications to clean or enlarge passageways, as well as to clean or form a variety of cavities. First, a tissue removal device is provided. The tissue removal device has an exchangeable drive shaft cartridge and a rotatable, radially expandable prime mover coupling. The exchangeable drive shaft cartridge includes a rotatable drive shaft socket carried by a drive shaft carriage; a longitudinally extendable tube extending distally from the drive shaft carriage; an elongated catheter having a proximal end portion which is operatively connected to a distal end portion of the longitudinally extendable tube; and a rotatable flexible drive shaft having proximal, intermediate and distal portions, the proximal portion being attached to the drive shaft socket, the intermediate portion being disposed primarily within the longitudinally extendable tube and the catheter, and the distal portion extending distally from the catheter and having a tissue removal implement. The prime mover coupling is carried by a prime mover carriage and connected to a prime mover for rotation therewith.

In accordance with this method, a length of the prime mover coupling is positioned within the drive shaft socket such that the prime mover coupling does not effectively engage an interior surface of the drive shaft socket. The prime mover coupling is then rotated at a speed sufficient to cause it to radially expand to effectively engage the drive shaft socket, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover. Rotation of the prime mover is then stopped, thereby disconnecting the drive shaft from the prime mover. If so desired, once the drive shaft is so disconnected from the prime mover, the exchangeable drive shaft cartridge can be replaced with another exchangeable drive shaft cartridge.

In atherectomy applications, the flexible drive shaft and the catheter are advanced over a guide wire into a body passageway of interest. The rest of the assembled device typically is also advanced over the guide wire, but remains outside the patient's body. The prime mover and the prime mover coupling are rotated at a speed sufficient to cause the prime mover coupling to radially expand to effectively engage the drive shaft socket, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover. The rotating flexible drive shaft and its tissue removal implement are advanced against the material to be removed. When the desired amount of material has been removed, the prime mover may be stopped or slowed down and the flexible drive shaft and the catheter are withdrawn from the patient's body. When rotation of the prime mover is stopped, the drive shaft is disconnected from the prime mover. If so desired, once the drive shaft is so disconnected from the prime mover, the exchangeable drive shaft cartridge can be replaced with another exchangeable drive shaft cartridge having a tissue removal implement of different size or even different design and the procedure spelled out above may be repeated on the same or a different passageway.

It should be noted that, for some medical applications, and even for some atherectomy applications, the use of a guide wire may not be necessary for some or all of the procedure. In some applications, special guiding catheters may be employed together with or instead of a guide wire.

In industrial applications, the catheter around the drive shaft may not be needed and there may be no need for either a guide wire or a guiding catheter. For other specific applications (both medical and non-medical), other components may be omitted from the exchangeable drive shaft cartridge or the prime mover coupling. For example, there may be no need for the longitudinally extendable tube.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of one embodiment of a rotational atherectomy device of the present invention showing the exchangeable drive shaft cartridge attached to the handle and illustrating the drive shaft carriage and the prime mover carriage interconnected to move together as a unit;

FIG. **2** is a perspective view of the device of FIG. **1** with the interconnected carriages moved distally toward a position where the drive shaft carriage becomes locked in a position which is convenient for detaching the drive shaft cartridge from the handle;

FIG. **3** is a top view of a broken-away portion of the device of FIG. **2**, illustrating the interlocking elements of the exchangeable drive shaft cartridge;

FIG. **4** is a partially cross sectional view similar to FIG. **3** showing an intermediate step in moving the drive shaft carriage to a position where the interlocking elements of the drive shaft cartridge become interlocked;

FIG. **5** is a partially cross sectional view similar to FIGS. **3** and **4** showing the interlocking elements of the exchangeable drive shaft cartridge in their interlocked position;

FIG. **6** is a view similar to FIG. **5**, but showing the interlocking elements of the exchangeable drive shaft cartridge in a side view;

FIGS. **7–9** schematically illustrate the process of disconnecting the drive shaft carriage from the prime mover carriage;

FIG. **10** is a perspective view similar to FIG. **1**, but illustrating the drive shaft carriage disconnected from the prime mover carriage;

FIG. **11** is a schematic cross sectional view taken along line **11—11** in FIG. **10** and showing how the exchangeable drive shaft cartridge is attached to a distal portion of the handle;

FIG. **12** is an enlarged view of the section outlined in FIG. **11**;

FIG. **13** is a perspective view similar to FIG. **10**, but showing the exchangeable drive shaft cartridge detached from the distal portion of the handle;

FIG. **14** is a schematic cross sectional view taken along line **14—14** in FIG. **13**;

FIG. **15** is a perspective view similar to FIG. **13**, showing the exchangeable drive shaft cartridge detached from a handle which has a somewhat different design of its distal portion;

FIG. **16** is a schematic cross-sectional view taken along line **16—16** of FIG. **15**;

FIG. **17** is a perspective view similar to FIG. **10**, but showing another exchangeable drive shaft cartridge attached to the distal portion of the handle;

FIG. **18** is a top view of a broken-away portion of the device of FIG. **17** showing the drive shaft carriage spaced from the prime mover carriage;

FIGS. **19** and **20** are top views illustrating the process of interconnecting the drive shaft carriage and the prime mover carriage;

FIG. **21** is a perspective view similar to FIG. **17**, but showing the drive shaft carriage and the prime mover carriage interconnected to move together as a unit;

FIG. **22** is a perspective view similar to FIG. **21**, but showing the carriages moved proximally so that the interlocking elements of the exchangeable drive shaft cartridge are spaced away from each other;

FIG. **23** is a perspective view similar to FIG. **22**, but wherein the rotational atherectomy device has been advanced over a guide wire;

FIG. **24** is a broken-away longitudinal cross sectional view of the drive shaft cartridge showing the interlocking elements of the exchangeable drive shaft cartridge spaced from one another;

FIG. **25** is a longitudinal cross sectional view similar to FIG. **24** showing the interlocking elements of the exchangeable drive shaft cartridge in their interlocked position;

FIG. **26** is a broken-away, longitudinal cross sectional view showing the drive shaft carriage spaced away from the prime mover carriage;

FIG. **27** is a schematic end view of the prime mover carriage taken along line **27—27** in FIG. **26**;

FIG. **28** is a schematic end view of the drive shaft carriage taken along line **28—28** in FIG. **26**;

FIGS. **29–31** are longitudinal cross sections illustrating the process of interconnecting the drive shaft carriage and the prime mover carriage;

FIG. **32** is similar to FIG. **31**, but wherein the rotational atherectomy device has been advanced over a guide wire;

FIG. **33** is a longitudinal cross sectional view similar to FIG. **32** showing the interconnected drive shaft and prime mover carriages being moved proximally to a position where the interlocking elements of the drive shaft cartridge become disconnected;

FIG. **34** is a longitudinal cross sectional view similar to FIG. **33** showing the interlocking elements of the exchangeable drive shaft cartridge spaced away from one another;

FIG. **35** is a longitudinal cross section similar to FIG. **34**, but illustrating the device in a perspective view;

FIG. **36** is an enlarged view of the section outlined in FIG. **34** illustrating that the flexible pins of the prime mover coupling do not contact an interior surface of the drive shaft socket when the prime mover is not rotating;

FIGS. **37–39** illustrate how the flexible pins of the prime mover coupling deflect into frictional engagement with the interior surface of the drive shaft socket upon increasingly rapid rotation of the prime mover;

FIG. **40** is a view similar to FIG. **36**, but illustrating an alternative embodiment of a base of the prime mover coupling;

FIG. **41** illustrates how the flexible pins of the prime mover coupling of FIG. **40** deflect into frictional engagement with the interior surface of the drive shaft socket upon rapid rotation of the prime mover;

FIG. **42** is an isolational view of the prime mover carriage shown in FIG. **26**;

FIG. **43** is a longitudinal cross sectional view similar to FIG. **42**, but illustrating how the flexible pins of the prime mover coupling can rub against an interior surface of the prime mover carriage upon rapid rotation of the prime mover when the prime mover carriage is not interconnected with the drive shaft carriage;

FIG. **44** is an enlarged view of the section outlined in FIG. **43**;

FIG. **45** is a longitudinal cross sectional view of a modified embodiment of a prime mover carriage which shows the carriage including a coupling shield carried by the prime mover coupling;

FIG. **46** is an enlarged view of the section outlined in FIG. **45**;

FIG. **47** is a longitudinal cross sectional view similar to FIG. **46**, but illustrating how the coupling shield restricts outward deflection of the distal ends of the flexible pins of the prime mover coupling upon rapid rotation of the prime mover when the prime mover carriage is not interconnected with the drive shaft carriage;

FIG. **48** is a longitudinal cross sectional view showing the modified prime mover carriage of FIG. **45** interconnected with a drive shaft carriage and illustrating how the coupling shield can be moved away from the distal ends of the pins to permit the pins to be received in the drive shaft socket;

FIG. **49** is an enlarged view of the section outlined in FIG. **48**;

FIG. **50** is a longitudinal cross sectional view similar to FIG. **49**, but illustrating how the flexible pins of the prime mover coupling engage the drive shaft socket upon rapid rotation of the prime mover;

FIG. **51** is a longitudinal cross sectional view similar to FIG. **34**, but illustrating a radially expandable prime mover coupling which employs an elastomeric, radially expandable tube;

FIG. **52** is an enlarged view of the section outlined in FIG. **51**;

FIG. **53** is a longitudinal cross sectional view similar to FIG. **52**, but illustrating how the free end of the radially expandable tube of the prime mover coupling engages the drive shaft socket upon rapid rotation of the prime mover;

FIG. **54** is a longitudinal cross sectional view similar to FIG. **52**, but illustrating a modified embodiment of the radially expandable tube;

FIG. **55** is a longitudinal cross sectional view similar to FIG. **54**, but illustrating how the free end of the radially expandable tube of the prime mover coupling engages the drive shaft socket upon rapid rotation of the prime mover;

FIG. **56** is a longitudinal cross sectional view similar to FIG. **54**, but illustrating a radially expandable prime mover coupling which employs flyweights instead of an elastomeric, radially expandable tube;

FIG. **57** is a longitudinal cross sectional view similar to FIG. **56**, but illustrating how the flyweights of the prime mover coupling engage the drive shaft socket upon rapid rotation of the prime mover;

FIG. **58** is a longitudinal cross sectional view similar to FIG. **56**, but illustrating a modified embodiment of the drive shaft socket which includes recesses for engaging the flyweights;

FIG. **59** is a longitudinal cross sectional view similar to FIG. **58**, but illustrating how the flyweights of the prime mover coupling engage the recesses of the drive shaft socket upon rapid rotation of the prime mover;

FIG. **60** is a longitudinal cross sectional view taken along line **60—60** of FIG. **34** and illustrating a flexible fluid supply tubing attached to the exchangeable drive shaft cartridge;

FIG. **61** is an enlarged view of that section outlined in FIG. **60** which shows where the fluid supply tubing delivers fluid to the drive shaft lumen;

FIG. **62** is an enlarged view similar to FIG. **61**, but illustrating a preferred embodiment wherein a heat shrinkable tubing has been shrunk onto a proximal length of an intermediate portion of the drive shaft;

FIG. **63** is an enlarged view of that section outlined in FIG. **60** which shows a dynamic seal for urging fluid away from a bearing supporting the prime mover;

FIG. **64** is a broken-away, longitudinal cross sectional view of the proximal portion of the handle;

FIG. **65** is a transverse cross sectional view taken along line **65—65** in FIG. **64** and illustrating the carriage brake in an unlocked position wherein the telescoping tube attached to the prime mover carriage is free to move longitudinally;

FIG. **66** is a cross sectional view similar to FIG. **65**, but shows the carriage brake in a locked position wherein the telescoping tube attached to the prime mover carriage is prevented from moving longitudinally;

FIG. **67** is a transverse cross sectional view taken along line **67**—**67** in FIG. **65** and illustrating how a removable leg is clamped onto the proximal portion of the handle.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **1** illustrates in perspective view one embodiment of an atherectomy device of the invention. The device desirably includes a handle **10**. The handle **10** has a proximal portion **12** which carries a prime mover carriage **200**, a distal portion **20** adapted to releasably hold an exchangeable drive shaft cartridge **80**, and an intermediate portion **14** which serves to connect the proximal and distal portions of the handle to one another.

The prime mover carriage **200** is longitudinally moveable with respect to the handle **10** by being connected to a telescoping tube **280** which is slidably received in the proximal portion **12** of the handle **10**. The prime mover carriage **200** carries a prime mover coupling **330** which is connected to a prime mover for rotation therewith. (The prime mover coupling **330** and the prime mover are not seen in FIG. **1**, but are discussed below in connection with FIGS. **26** and **36–39**, for example.)

The exchangeable drive shaft cartridge **80** includes a drive shaft carriage **150**, a longitudinally extendable tube **100** extending distally from the drive shaft carriage, an elongated catheter **70** operatively connected to a distal end portion of the longitudinally extendable tube, and a rotatable flexible drive shaft **60**. The flexible drive shaft **60** is desirably rotatable over a guide wire **104** and includes a proximal portion **62**, an intermediate portion **64** and a distal portion **66**. The proximal portion **62** of the drive shaft **60** is attached to a drive shaft socket **180** carried by the drive shaft carriage **150**. (The proximal portion **62** of the drive shaft **60** and the drive shaft socket **180** are not shown in FIG. **1**, but are discussed below in connection with FIGS. **24** and **25**, for example.) The intermediate portion **64** of the drive shaft **60** is disposed primarily within the longitudinally extendable tube **100** and the catheter **70** and therefore is not visible in FIG. **1**. The distal portion **66** of the drive shaft extends distally from the catheter **70** and includes a tissue removal implement **68**. The tissue removal implement in the illustrated embodiment comprises an enlarged diameter section of the drive shaft which has a generally conical proximal portion and a generally convex distal portion. The convex distal portion is covered with an abrasive material to define an abrasive segment **69** of the drive shaft. (Such a tissue removal implement is described in U.S. patent application Ser. No. 08/679,470, filed 15 Jul. 1996.) It should be understood that any suitable tissue removal implement **68** may be used, including an eccentric tissue removal implement (such as is described in U.S. patent application Ser. No. 08/911,586, filed 14 Aug. 1997) or the diamond-coated burr proposed by Auth in U.S. Pat. No. 4,990,134.

In FIG. **1**, the drive shaft carriage **150** and the prime mover carriage **200** are interconnected so they can be moved together as a unit.

As is described in more detail below (e.g., in connection with FIGS. **36–39**), the prime mover coupling **330** of the prime mover carriage **200** is adapted to effectively engage the drive shaft socket **180** of the drive shaft carriage **150** upon sufficiently rapid rotation of the prime mover. This will, in turn, cause the drive shaft socket **180** and the drive shaft **60** to rotate together with the prime mover coupling **330** and the prime mover. However, when the prime mover is not rotating, the prime mover coupling **330** becomes disengaged from the drive shaft socket **180**, thereby permitting the drive shaft carriage **150** to be disconnected from the prime mover carriage **200**. As a result, one exchangeable drive shaft cartridge **80** can be disconnected from the distal portion **20** of the handle **10** and replaced by another exchangeable drive shaft cartridge.

The exchangeable drive shaft cartridge **80** comprises a generally tubular housing **110**. In a preferred embodiment, the distal portion **20** of the handle **10** includes at least one complementary clamp **28** for releasably holding the tubular housing **110** of the drive shaft cartridge **80** within a longitudinally extending groove **24** which is formed in the distal portion **20** of the handle. In this embodiment, the longitudinally extending groove **24** (better seen in FIGS. **13** and **14**, for example) is upwardly open and is defined by a pair of opposing walls **22**.

As is described in more detail below (e.g., in connection with FIGS. **24** and **25**), the longitudinally extendable tube **100** includes outer **82** and inner **90** telescoping tubes. The outer telescoping tube **82** is connected to the drive shaft carriage **150** and the inner telescoping tube **90** is connected to a distal end piece (**130** in FIG. **24**, for example) of the tubular housing **110**. The outer telescoping tube **82** is slidably received in an elongated annular space **120** defined between the inner surface of the tubular housing **110** and an outer surface of the inner telescoping tube **90**.

FIGS. **2–10** schematically illustrate a preferred sequence for disconnecting the drive shaft carriage **150** from the prime mover carriage **200**. First, as shown in FIG. **2**, the interconnected carriages **150** and **200** are moved forward to shorten the longitudinally extendable tube **100** so that its telescoping tubular components are not damaged when the drive shaft cartridge **80** is removed from the longitudinally extending groove **24** in the distal portion **20** of the handle **10**.

FIGS. **3–6** illustrate a preferred embodiment wherein the tubular housing **110** and the drive shaft carriage **150** carry complementary fittings for releasably locking the drive shaft carriage **150** to the tubular housing **110** when a majority of the length of the outer telescoping tube **82** is received within the tubular housing **110** of the drive shaft cartridge **80**. In a preferred embodiment, these complementary fittings comprise at least one tab **114** carried by one of the tubular housing **110** and the drive shaft carriage **150** and a flange **154** carried by the other one of the tubular housing **110** and the drive shaft carriage **150**.

In the embodiment seen in FIGS. **3–6**, the proximal end of the tubular housing **110** is provided with a plurality of proximally extending resilient tabs **114** which have inwardly-extending shoulders **116** adjacent their proximal ends. If so desired, the tabs may all be integrally formed with an annular proximal collar **112** which is attached to the proximal end of the tubular housing **110**. The drive shaft carriage **150** is provided with a radially outwardly extending flange **154**. A groove **156** may be provided proximally of the flange **154** for receiving the shoulders **116** of the resilient tabs **114** of the tubular housing **110**.

Equivalently, the flange **154** may be carried not by the drive shaft carriage **150**, as shown in the illustrated embodiment, but instead by the outer telescoping tube **82**. This will permit the user to releasably interlock the outer telescoping tube **82** and the tubular housing **110**, thereby protecting the telescoping tubes (**82** and **90**) of the longitudinally extendable tube **100** from damage when the drive shaft cartridge **80** is removed from the longitudinally extending groove **24** in the distal portion **20** of the handle **10**.

FIG. **3** is a top view of the relevant portions of FIG. **2**. In the position shown in FIG. **3**, most of the length of the outer telescoping tube **82** is received within the tubular housing **110** and the flange **154** is positioned close to the tabs **114**. As shown in FIG. **4**, further distal movement of the interconnected carriages **150** and **200** causes the proximal ends of the resilient tabs **114** to deflect radially outwardly so the shoulders **1 16** can move over the flange **154**. As soon as the carriages are moved distally a little further, the shoulders **116** of the resilient tabs **114** are received in the groove **156** behind the flange **154**, as shown in FIGS. **5** and **6**. Since the shoulders **116** of the tabs **114** are free to circumferentially slide in the groove **156**, the outer telescoping tube **82** is free to rotate with respect to both the tubular housing **110** and the inner telescoping tube **90** when the drive shaft carriage **150** is releasably locked to the tubular housing **110** of the drive shaft cartridge **80**. Usually, the entire atherectomy device, including the drive shaft **60**, is pulled off the guide wire **104** before the carriages **150** and **200** are disconnected.

As noted above, the drive shaft carriage **150** and the prime mover carriage **200** are designed to be releasably interconnected to move together as a unit. FIGS. **7–10** illustrate the process of disconnecting the drive shaft carriage **150** from the prime mover carriage **200**. The carriages **150** and **200** are each provided with fittings which releasably interconnect the carriages. Desirably, at least one of the fittings is free to rotate with respect to the carriage with which it is associated to facilitate connection of the carriages to one another.

These fittings desirably comprise mating components of a bayonet joint, i.e., a joint in which two mechanical parts are so interconnected that they cannot be separated by longitudinal movement. In the embodiment shown in the drawings, these mating components comprise pegs **160** carried by the drive shaft carriage **150** and slots **310** formed in a bayonet collar **300** carried by the prime mover carriage **200**. The bayonet collar **300** preferably is rotatable about the prime mover carriage **200**.

There preferably are at least three pegs **160** equiangularly spaced about the drive shaft carriage and an equal number of slots **310** which are equiangularly spaced about the bayonet collar **300**. The pegs **160** slide within the slots **310** when the bayonet collar **300** is rotated. As illustrated in FIGS. **7–9**, the operator manually grasps the drive shaft carriage **150** with one hand and the bayonet collar **300** with the other hand. The operator then rotates the bayonet collar until the pegs **160** reach the inlets **312** of the slots **310**, as shown in FIG. **8**. Once the pegs **160** reach the inlets **312** of the slots, the operator moves the bayonet collar **300** proximally, thereby moving the prime mover carriage **200** away from the drive shaft carriage **150**, as shown in FIGS. **9** and **10**.

FIGS. **10–14** schematically illustrate how the exchangeable drive shaft cartridge **80** can be disconnected from the distal portion **20** of the handle **10**. In particular, FIGS. **10–12** illustrate how the exchangeable drive shaft cartridge **80** is held in the distal portion **20** of the handle **10** while FIGS. **13** and **14** illustrate the exchangeable drive shaft cartridge disconnected from the distal portion **20** of the handle.

As noted above, the distal portion **20** of the handle **10** is designed to releasably hold the exchangeable drive shaft cartridge **80**. In the illustrated embodiments, the distal portion **20** of the handle **10** includes a pair of opposing side walls **22** which define a longitudinally extending groove **24** (best seen in FIGS. **13** and **14**). This groove **24** is sized to releasably hold a length of the exchangeable drive shaft cartridge **80** therein. Although the longitudinally extending groove **24** may be oriented in a variety of ways, in the preferred embodiment shown in the drawings, the groove **24** is upwardly open to make it easier to insert and remove the exchangeable drive shaft cartridge **80**.

In use, an operator may wish to grasp the handle **10** around the distal portion **20**. The longitudinally extending groove **24** desirably has a depth greater than the outer diameter of the tubular housing **110** in order to limit manual pressure on the tubular housing **110** when a user grasps the handle around the groove. Optimally, the walls **22** defining the groove **24** are high enough to extend above the tubular housing **110**, substantially preventing any inadvertent deformation of the tubular housing **110** which may interfere with optimal operation of the longitudinally extendable tube **100** (e.g., by making it more difficult to move the outer telescoping tube **82** with respect to the tubular housing **110** and the inner telescoping tube **90**).

The distal portion **20** of the handle preferably also includes at least one clamp **28** for retaining the exchangeable drive shaft cartridge **80** in the groove **24**. In the embodiment of FIGS. **10–14**, there are two such clamps **28** and these clamps are spaced from one another longitudinally along the distal portion of the handle. (In the embodiment of FIGS. **15** and **16**, there is only one such clamp **34**, but that clamp **34** is longer to ensure that the exchangeable drive shaft cartridge is securely held in the desired position.) In addition, these clamps **28** (or the clamp **34**) may also serve to limit longitudinal movement of the exchangeable drive shaft cartridge **80** within the longitudinally extending groove **24**. For example, the proximal of the two clamps **28** (or the proximal end of the clamp **34**) preferably abuts the proximal collar **112** which carries the tabs **114** of the tubular housing **110** and the distal of the two clamps **28** (or the distal end of the clamp **34**) preferably abuts a distal collar **132** of the tubular housing.

If so desired, one or more elements of the distal portion **20** of the handle can be integrally formed to make manufacturing easier. In the embodiment illustrated in FIGS. **10–14**, the walls **22** defining the groove **24**, the clamps **28**, and the base **26** of the distal portion **20** of the handle are all integrally formed as a single component. In the embodiment of FIGS. **15** and **16**, the corresponding elements of the distal portion **20** of the handle are instead formed from two separate mating elements **30** and **32**. In particular, the clamp **34** includes two opposing sides. One side of the clamp **34** is integrally formed with the wall **22** which is part of the mating element **30**. The other side of the clamp **34** is integrally formed with the opposing wall **22** which is part of the other mating element **32**. These two mating elements **30** and **32** can be attached to one another, such as by a suitable adhesive or by appropriately interlocking fittings.

One can remove the exchangeable drive shaft cartridge **80** from the distal portion **20** of the handle **10** simply by lifting the cartridge **80** vertically out of the upwardly open groove **24**. Once the exchangeable drive shaft cartridge **80** is removed as shown in FIGS. **13** and **14**, another exchangeable drive shaft cartridge (e.g., a cartridge with a larger diameter abrasive tissue removing implement) can be inserted in the groove **24** in the distal portion **20** of the handle. The distal portion **20** of the handle, or the entire handle **10**, can be formed of a sterilizable material such as titanium so the distal portion of the handle, or the entire handle, can be reused.

FIG. **17** illustrates another exchangeable drive shaft cartridge **80** inserted in the groove **24** in the distal portion **20** of the handle. The cartridge **80** shown in FIG. **17** is identical to the cartridge shown in the preceding figures, except that the new cartridge **80** has a larger diameter tissue removal implement **68'**, as may be evident from comparing FIGS. **10** and **17**. The process of inserting the exchangeable drive shaft cartridge **80** in the distal portion **20** of the handle **10** is essentially the reverse of the process in which it is disconnected from the handle. First, the operator should longitudinally align the exchangeable drive shaft cartridge **80** with the distal portion **20** of the handle such that both clamps **28** are touching the tubular housing **110** between the proximal collar **112** and distal collar **132**. Once the exchangeable drive shaft cartridge **80** is properly positioned, it simply may be pushed downwardly into the upwardly open groove **24** until it snaps in place in the clamps **28**.

One of the opposing walls **22** includes a slot **23** (best seen in FIGS. **13** and **15**, for example) for receiving a flexible fluid supply tubing **360** therein. As described more fully below, this flexible fluid supply tubing **360** is attached to the exchangeable drive shaft cartridge **80** and supplies fluid to the drive shaft and guide wire lumens.

FIGS. **18–20** are top views schematically illustrating how one may interconnect the drive shaft carriage **150** and the prime mover carriage **200**. First, as shown in FIG. **18**, the inlets **312** of the slots **310** in the bayonet collar **300** should be longitudinally aligned with the pegs **160** of the drive shaft carriage **150**. The inlets **312** of the slots **310** are desirably relatively wide to simplify such longitudinal alignment. Once the slots **310** and the pegs **160** are properly aligned, the prime mover carriage and the drive shaft carriage can be moved toward one another. As shown in FIG. **19**, this may be accomplished simply by moving the prime mover carriage **200** distally until each of the pegs **160** is received in the inlet **312** of a slot **310** and preferably contacts the longer guiding wall **314** of the inlet **312**. In the illustrated embodiment, the longer guiding wall **314** of each inlet **312** forms an obtuse angle with the posterior wall **316** of the leg **322** of the slot **310**.

Once the pegs **160** are received in the inlets **312** of the slots **310**, the bayonet collar **300** and the drive shaft carriage **150** are rotated with respect to each other until each peg **160** reaches the closed end of a leg **322** and is seated in a small recess **320** formed in the anterior wall **318** of the leg **322**, as shown in FIG. **20**. The leg **322** of each slot **310** extends generally circumferentially about the bayonet collar **300**. Preferably, the leg **322** also extends such that its closed end is positioned slightly proximally with respect to its inlet end. As explained in more detail below in connection with FIGS. **29–31**, this will serve to properly position the prime mover coupling **330** and the drive shaft socket **180** with respect to one another.

FIG. **21** illustrates the interconnected carriages **150** and **200** in their most distal position. In this position, the tubular housing **110** and the drive shaft carriage **150** are in their interlocked position. FIG. **22** illustrates the interconnected carriages **150** and **200** moved proximally, thereby disconnecting the drive shaft carriage **150** from the tubular housing **110** so the telescoping tubes **82** and **90** can slide with respect to one another. FIGS. **17–22** illustrate a process wherein the carriages **150** and **200** are interconnected before the drive shaft carriage **150** is disconnected from the tubular housing **110**. It should be understood, however, that the order of these two steps can be reversed and the drive shaft carriage **150**, together with the outer telescoping tube **82**, may be moved proximally before the carriages **150** and **200** are interconnected.

As noted above, the handle **10** includes a proximal portion **12**, a distal portion **20** and an intermediate portion **14** extending therebetween. In the illustrated embodiment, this intermediate portion **14** comprises an elongated rod or tube which connects the proximal **12** and distal **20** portions of the handle to one another. As discussed below in connection with FIG. **64**, outer **280** and inner **290** proximal telescoping tubes are slidably received in the proximal portion **12** of the handle. Distal ends of these telescoping tubes **280** and **290** are connected to the prime mover carriage. The elongated rod of the intermediate portion **14** of the handle extends generally parallel to these telescoping tubes **280** and **290** and is spaced therefrom a distance sufficient to permit both the drive shaft carriage and the prime mover carriage to move parallel to the elongated rod of the handle. Thus, when the drive shaft carriage **150** and the prime mover carriage **200** are interconnected, they can move together as a unit both longitudinally and rotationally with respect to the handle **10**. It should be noted that when the interconnected carriages **150** and **200** are moved longitudinally, this will move the drive shaft **60** and its tissue removal implement **68** along a vascular lumen of the patient's body.

FIG. **23** illustrates the assembled rotational atherectomy device advanced over the guide wire **104**. The device may be advanced over the guide wire at any time after the two carriages **150** and **200** have been interconnected. In clinical use, the guide wire is first advanced across a lesion in the patient's vessel and only then the assembled device is advanced over the guide wire.

FIGS. **24** and **25** are broken-away longitudinal cross sectional views of one preferred embodiment of an exchangeable drive shaft cartridge **80** of the invention. FIG. **28** is a proximal end view of the same cartridge.

As described above, the exchangeable drive shaft cartridge **80** includes a drive shaft carriage **150**, a longitudinally extendable tube **100** extending distally from the drive shaft carriage, an elongated catheter **70** having a proximal end portion **72** which is operatively connected to a distal end portion of the longitudinally extendable tube **100**, and a rotatable flexible drive shaft **60**. The drive shaft **60** is formed of a helically wound wire and the wire turns of the drive shaft define a guide wire lumen within which a guide wire may be received. The guide wire **104** is not shown in FIGS. **24**, **25** and **28**, but is shown in FIGS. **32–35**, for example.

The flexible drive shaft **60** includes a proximal portion **62**, an intermediate portion **64**, and a distal portion **66**. The distal portion **66** of the drive shaft is not shown in FIGS. **24**, **25** and **28**, but is described above in connection with FIG. **1**. The proximal portion **62** of the drive shaft is attached to the drive shaft socket **180** for rotation therewith. The drive shaft socket **180** is carried by the drive shaft carriage **150** and is supported therein by a ball bearing **172**. The intermediate portion **64** of the drive shaft is disposed primarily within the longitudinally extendable tube **100** and the catheter **70**. Most of the length of the intermediate portion **64** of the drive shaft is disposed in the catheter **70**. Only a proximal length of the intermediate portion **64** is shown in FIGS. **24** and **25** since most of the length of the catheter **70** is not shown in these drawings.

The longitudinally extendable tube **100** and the catheter **70** each have a lumen. These lumens together define a drive shaft lumen **85** within which a majority of the length of the drive shaft is received. Fluid supplied to the drive shaft lumen **85** passes between wire turns of the drive shaft **60** into the guide wire lumen.

FIG. **24** shows the longitudinally extendable tube **100** at its maximum length and FIG. **25** shows the longitudinally extendable tube **100** at its minimum length. In the preferred embodiment shown in these drawings, the longitudinally extendable tube **100** includes outer **82** and inner **90** telescoping tubes, the outer telescoping tube **82** being connected to the drive shaft carriage **150** and the inner telescoping tube **90** being connected to a distal end piece **130** of the tubular housing **110**. The inner telescoping tube **90**, or at least a distal length thereof, defines a distal end portion of the longitudinally extendable tube **100**.

The outer telescoping tube **82** is slidably received in an elongated annular space **120** defined between the inner surface **122** of the tubular housing **110** and an outer surface **92** of the inner telescoping tube **90**. The outer telescoping tube **82** is moveable within that annular space **120** both longitudinally and rotationally with respect to both the tubular housing **110** and the inner telescoping tube **90**. Desirably, the inner surfaces of both the inner **90** and outer **82** telescoping tubes are provided with a low-friction lining **94** and **84**, respectively. The lining **94** of the inner telescoping tube **90** helps minimize friction with the drive shaft **60** as it is rotated and moved proximally and distally around a guide wire. The lining **84** of the outer telescoping tube **82** helps minimize friction between the telescoping tubes as the outer tube is moved with respect to the inner telescoping tube.

These linings may be made from any suitable material, such as polytetrafluoroethylene tubing. In the illustrated embodiment, the linings **84** and **94** may be held in place using flanges (**86** and **96**, respectively) formed at their ends. If so desired, the separate linings may be omitted and the tubes **82** and **90** themselves may be made of a low friction material.

To prevent the disassembly of the longitudinally extendable tube **100**, proximal movement of the outer telescoping tube **82** is limited by a pair of stops, one stop **88** being carried adjacent the distal end of the outer telescoping tube **82** and the other stop **118** being carried adjacent the proximal end of the tubular housing **110**. To limit friction between the outer telescoping tube **82** and the tubular housing **110**, these stops **88** and **118** may be formed of a low friction material such as polytetrafluoroethylene. If so desired, one or both of these stops **88** and **118** can be formed as an integral part of the outer telescoping tube **82** or the tubular housing **110**. This is particularly advantageous if the outer telescoping tube **82** or the tubular housing **110** is made from a low friction material.

The drive shaft carriage **150** is carried adjacent the proximal end of the outer telescoping tube **82** . The drive shaft carriage generally includes an outer shell **152** which is attached to the outer telescoping tube **82** and a carriage core **170** which carries the drive shaft socket **180**. The carriage core **170** desirably includes a recess for receiving a bearing **172** which supports the drive shaft socket **180**. The bearing optimally is a ball bearing which is held in place by a stop ring **174**. The pegs **160** of the drive shaft carriage **150** are attached to and extend radially outwardly from the outer shell **152**. The proximal end portion of the outer shell **152** includes an abutting surface **162** and two guiding surfaces **168** and **166**. Both guiding surfaces are generally conical in shape, one of them being an outer guiding surface **168** and the other being an inner guiding surface **166**.

The drive shaft socket **180** includes a tubular shaft **190**, a disc **186** and a proximally extending engagement ring **182**. The engagement ring **182** defines an interior engagement surface **184** of the socket **180**. In a preferred embodiment, the interior engagement surface **184** of the socket **180** is generally cylindrical, but it may have a somewhat different shape, e.g. a generally frustoconical shape. The proximal surface of the disc **186** defines a proximally oriented face **188** of the drive shaft socket **180**. In the illustrated embodiment, the tubular shaft **190** is comprised of an outer tubular shaft portion **192** and an inner tubular shaft portion **194**. Desirably, the outer tubular shaft portion **192**, the disc **186** and the engagement ring **182** are integrally formed as a single element while the inner tubular shaft portion **194** is formed as a separate element. The inner tubular shaft portion **194** is glued or otherwise attached to the rest of the drive shaft socket **180** for rotation therewith. If so desired, the entire drive shaft socket **180**, including both portions of the tubular shaft, may be integrally formed as a single component.

Preferably, the inner tubular shaft portion **194** extends proximally of the face **188** of the disc **186** to define a central extension **196** of the socket. As shown in the drawings, this central extension **196** is tubular and includes a central lumen having the same diameter as the rest of the inner tubular shaft portion **194** so that the proximal portion **62** of the flexible drive shaft may extend proximally to the proximal end of the central extension **196** of the drive shaft socket **180**. It should be understood that the central extension need not be tubular and it may be provided with a different outer shape, e.g. it may be conical in shape.

The carriage core **170** can be press fitted, glued or otherwise attached to the outer shell **152** of the drive shaft carriage **150**. These components, as well as many other components shown as separate parts in the drawings may be integrally formed with one another.

As described in more detail below, fluid is supplied to the exchangeable drive shaft cartridge **80** distally of the drive shaft socket **180**, and preferably adjacent the distal end of the longitudinally extendable tube **100**. The distal end portion of the longitudinally extendable tube **100** is connected to the distal end piece **130** of the housing. A tubular proximal extension of the distal end piece **130** is connected to the tube comprising most of the length of the tubular housing **110** and defines the annular distal collar **132** of the tubular housing. A tubular distal extension **134** of the distal end piece **130** is adapted to receive a bulkhead **140** therein. The bulkhead **140** is disposed between and operatively connects the distal end portion of the longitudinally extendable tube **100** and the proximal end portion **72** of the catheter **70**. The bulkhead **140** includes a fluid-receiving recess **144** positioned distally of a narrow opening **145** which defines a reduced diameter segment of the drive shaft lumen **85**. As discussed more fully below (e.g., in connection with FIGS. **60–62**), the bulkhead **140** also includes a passageway **142** through which fluid may enter the fluid-receiving recess **144** of the bulkhead **140**.

The proximal end portion **72** of the catheter desirably has a flange **74** at its proximal end. This flange **74** may be held between the bulkhead **140** and a washer **146** to keep the catheter in place. In a preferred embodiment, the proximal end portion **72** of the catheter is supported by a strain relief **76** which abuts the washer **146**. The bulkhead **140** and the washer **146** can be held in place by an end cap **152** which is attached to the tubular distal extension **134** of the distal end piece **130** of the tubular housing **110**.

In the embodiment seen in FIGS. **24** and **25**, the proximal end of the tubular housing **110** is provided with a plurality of proximally extending resilient tabs **114** which have inwardly-extending shoulders **116** adjacent their proximal ends. These tabs may all be integrally formed with the annular proximal collar **112** attached to the proximal end of the tubular housing **110**. The outer shell **152** of the drive shaft carriage **150** is provided with a radially outwardly extending flange **154** and a groove **156** positioned proximally of the flange **154** for receiving the shoulders **116** of the resilient tabs **114** of the tubular housing **110**.

In FIG. **24**, the longitudinally extendable tube **100** is at its maximum length, wherein the outer telescoping tube **82** is moved proximally with respect to both the tubular housing **110** and the inner telescoping tube **90** until the stops **88** and **118** engage one another. In FIG. **25**, however, the longitudinally extendable tube **100** is at its minimum length, wherein a majority of the length of the outer telescoping tube **82** has been received within the tubular housing **110**. In this position, the shoulders **116** of the resilient tabs **114** are received in the groove **156** behind the flange **154**, thereby releasably locking the drive shaft carriage **150** to the tubular housing **110**. Since the shoulders **116** of the tabs **114** are free to circumferentially slide in the groove **156**, the outer telescoping tube **82** is free to rotate with respect to both the tubular housing **110** and the inner telescoping tube **90** when the drive shaft carriage **150** is releasably locked to the tubular housing **110** of the drive shaft cartridge **80**.

The prime mover carriage **200** is shown in FIGS. **26** and **27**. The prime mover carriage **200** includes a prime mover housing **210** which carries the bayonet collar **300** and the prime mover together with the prime mover coupling **330**. The prime mover can be any device which can rotate the prime mover coupling **330** at sufficiently high speed. Preferably, though, the prime mover is a gas driven prime mover which generally comprises a turbine wheel **250** mounted on a prime mover shaft **230** for rotation therewith. The turbine wheel **250** is received in a turbine recess in the prime mover housing **210** and is driven by means of a compressed gas, e.g. air or nitrogen. As seen in FIG. **1**, the preferred embodiment of the invention includes a flexible gas supply tube **36** which is attached to the distal portion **12** of the handle **10**. This flexible gas supply tube **36** supplies compressed gas to a pneumatic guide wire clamp (not shown), which is retained in the distal portion **12** of the handle. The turbine wheel **250** is driven by compressed gas supplied through the flexible U-shaped linking tube **38**, which is in fluid communication with the flexible gas supply tube **36**. Gas driven turbines and pneumatic guide wire clamps are well known in the art (see, e.g., Auth et al. U.S. Pat. No. 5,314,407, the teachings of which are incorporated herein by reference) and need not be discussed in detail here.

The prime mover shaft **230** can be integrally formed as a single elongate tube. In the embodiment shown in FIG. **26**, though, the prime mover shaft **230** includes a shorter outer tubular portion **240** and a longer inner tubular portion **242**. The turbine wheel **250** is mounted on the outer tubular portion **240** of the prime mover shaft. The inner tubular portion **242** of the prime mover shaft is secured (e.g., glued) within the outer tubular portion **240**. The longer inner tubular portion **242** extends both distally and proximally of the shorter outer tubular portion **240**. The longer inner tubular portion **242** defines a guide wire lumen **236** of the prime mover shaft. In the embodiment shown in the drawings, a helically wound coil **238** is disposed within the guide wire lumen **236** of the prime mover shaft. The coil **238** is rotatable together with the prime mover and is desirably oriented such that it will urge fluid proximally when the prime mover is rotated. The distal end **232** of the inner tubular portion **242** of the prime mover shaft is flared outwardly so that a proximal length of the central extension **196** of the drive shaft socket **180** can slide more easily into the guide wire lumen **236** of the prime mover shaft **230**.

The prime mover shaft **230** is desirably supported within the prime mover housing **210** by at least one bearing. Preferably, the prime mover shaft **230** is supported by two bearings, one of which is positioned distally and the other of which is positioned proximally of the turbine wheel **250** of the prime mover. Both the distal bearing **252** and the proximal bearing **254** are mounted on the outer tubular portion **240** of the prime mover shaft. A coupling base **340** of the rotatable, radially expandable prime mover coupling **330** is secured to the prime mover shaft **230** distally of the distal bearing **252**. In the illustrated embodiment, the coupling base **340** is attached to the outer tubular portion **240** of the prime mover shaft **230**. In the embodiment shown in FIG. **26**, the prime mover coupling **330** includes at least two flexible pins **332** which are anchored adjacent their proximal ends to the coupling base **340**. As seen in FIG. **27**, there are six pins **332** and they are spaced equiangularly about the axis of the coupling base **340**.

A rotor **260** of an optical tachometer is mounted on the prime mover shaft proximally of the proximal bearing **254**. In the illustrated embodiment, the rotor **260** is mounted on the outer tubular portion **240** of the prime mover shaft **230**. The outer surface of the rotor **260** may include a pair of diametrically opposed concave reflectors (**262** in FIG. **60**). As detailed in U.S. Pat. No. 5,314,407, a rotor having diametrically opposed reflective areas can be used in conjunction with a pair of fiber optic cables (**264** in FIG. **1**, for example) to monitor the rotational speed of the prime mover.

The bearings **252** and **254** can be attached to the prime mover housing **210** to support the prime mover shaft **230**. In the embodiment shown in FIG. **26**, the distal bearing **252** is attached directly to the prime mover housing **210** while the proximal bearing **254** is attached to a proximal bearing support **256** which is, in turn, attached to the proximal end portion of the prime mover housing **210**.

A proximal bulkhead **270** of the prime mover carriage **200** is secured to the prime mover housing **210**. This can be done either by gluing the proximal bulkhead **270** to the proximal bearing support **256** or by passing screws through holes in the proximal bearing support and securing the screws directly to the prime mover housing **210**. Two moveable proximal telescoping tubes **280** and **290** are secured to and extend proximally from the proximal bulkhead **270**. The tubes may be secured to the proximal bulkhead **270** by a proximal cap **272** and a ring **234**. As described in more detail below in connection with FIG. **64**, for example, both of the proximal telescoping tubes are slidably received in the proximal portion **12** of the handle. The proximal bulkhead **270** also carries a short collar **276**. The distal end of the short collar **276** is in fluid communication with the proximal end of the guide wire lumen **236** of the prime mover shaft **230** while the proximal end of the short collar **276** is in fluid communication with the proximal inner telescoping tube **290**. Desirably, a small gap is provided between the short collar **276** and the proximal end of the inner tubular portion **242** of the prime mover shaft so the guide wire lumen **236** of the prime mover shaft may also be in fluid communication with a fluid drainage outlet **278** in the proximal bulkhead **270**.

The prime mover housing **210** includes a distally-facing abutting surface **214** which is adapted to abut the abutting surface **162** of the outer shell **152** of the drive shaft carriage. A proximally extending annular recess **212** may be positioned radially inwardly of this abutting surface **214** to receive the proximal end portion of the outer shell **152** of the drive shaft carriage **150**. A flange **216** may extend radially outwardly from the distal portion of the prime mover housing **210** to engage an interior shoulder **302** adjacent the proximal end of the bayonet collar **300**.

The prime mover housing **210** also includes a guiding sleeve **220** which extends distally beyond the abutting surface **214** of the prime mover housing **210** to surround and protect the prime mover coupling **330**. This guiding sleeve **220** is sized to be slidably received within the outer shell **152** of the drive shaft carriage and helps to align the prime mover coupling **330** with the drive shaft socket **180**. To facilitate easy entry of the guiding sleeve **220** into the outer shell **152** of the drive shaft carriage, the distal end **222** of the guiding sleeve may be beveled.

FIGS. **18–20**, discussed above, are top views schematically illustrating how one may interconnect the drive shaft carriage **150** and the prime mover carriage **200**. As explained previously, this is accomplished by aligning the pegs **160** with the inlets **312** of the slots **310** of the bayonet collar and moving the two carriages **150** and **200** toward one another. Once the pegs **160** are received in the inlets **312** of the slots **310**, the bayonet collar and the drive shaft carriage can be rotated with respect to one another until each of the pegs is seated in a recess **320** formed in the anterior wall **318** of the leg **322** of a slot **310**.

FIGS. **26** and **29–31** illustrate essentially the same process of interconnecting the carriages **150** and **200**, but in a longitudinal cross sectional view which shows the positions of the prime mover coupling **330** and the drive shaft socket **180**. These drawings show how the drive shaft carriage **150** and the prime mover carriage **200** can be moved longitudinally from a non-operational position wherein the prime mover coupling **330** is spaced from the drive shaft socket **180** (FIG. **26**) to an operational position wherein a length of the prime mover coupling **330** is received within the drive shaft socket **180** (e.g., FIG. **31**). In the operational position shown in FIG. **31**, the drive shaft carriage **150** and the prime mover carriage **200** are interconnected to move together as a unit to move the drive shaft **60** and its tissue removal implement (**68** in FIG. **1**, for example) along a vascular lumen of a patient's body (not shown).

In moving from the position shown in FIG. **26** to the position shown in FIG. **29**, the drive shaft carriage **150** and the prime mover carriage **200** are moved longitudinally toward one another. In so doing, the guiding sleeve **220** of the prime mover housing **210** is slidably received within a proximal length of the outer shell **152** of the drive shaft carriage **150**. As noted above, the distal end **222** of the guiding sleeve **220** is beveled and the proximal end portion of the outer shell **152** includes a conical inner guiding surface **166**. This beveled end **222** and the inner guiding surface **166** facilitate easy entry of the guiding sleeve **220** into the outer shell **152** of the drive shaft carriage. The guiding sleeve **220** should be sized to be fairly closely received within the outer shell **152** of the drive shaft carriage. As shown in FIGS. **29–31**, the outer surface of the guiding sleeve **220** can thus slide against the inner surface of the outer shell **152** to align the prime mover coupling **330** with the drive shaft socket **180**.

Turning to FIG. **29**, the pegs **160** of the drive shaft carriage have just been received in the inlets of the slots **310** in the bayonet collar **300**. (In the cross sectional view of FIGS. **29–31**, only a single peg **160** and a single slot **310** are visible, but there are three pegs **160** and three slots **310** in the illustrated embodiment.) In this position, a majority of the length of the guiding sleeve **220** is received within the outer shell **152** of the drive shaft carriage **150** and the proximal end portion of the outer shell **152** is starting to be received in the annular recess **212** in the prime mover housing **210**. The free distal ends of the pins of the prime mover coupling **330** have also started to be received within the drive shaft socket **180**.

In FIG. **30**, the bayonet collar **300** has been rotated about the prime mover housing **210** (a central element of the prime mover carriage **200**) to slide the pegs **160** of the drive shaft carriage along the anterior wall (**318** in FIGS. **18–21**) of the slot **310**. In a preferred embodiment, the closed end of the leg **322** of each slot is positioned proximally of the inlet end of the leg. As a result, the pegs **160** of the drive shaft carriage **150** will slide along the anterior walls of the slots **310** as the bayonet collar **300** is rotated, urging the pins **160** proximally with respect to the bayonet collar **300**.

As the pins **160** of the drive shaft carriage move proximally with respect to the bayonet collar **300**, the interior shoulder **302** of the bayonet collar will pull against the flange **216** of the prime mover housing **210**. As a result, the pegs **160** and the bayonet collar **300** move the drive shaft carriage **150** and the prime mover carriage **200** closer to one another. As shown in FIG. **30**, this will cause the proximal end portion of the outer shell **152** of the drive shaft carriage **150** to be more fully received in the annular recess **212** of the prime mover housing **210**. Desirably, the proximal end portion of the outer shell **152** includes a conical outer guiding surface **168** which may help more precisely align the carriages **150** and **200** with respect to one another. FIG. **30** also shows the central extension of the drive shaft socket **180** starting to be received in the guide wire lumen of the prime mover shaft **230**. The flared distal end of the prime mover shaft **230** will help guide the central extension of the drive shaft socket **180** into place even if these two parts are slightly misaligned.

FIG. **31** illustrates the drive shaft carriage **150** and the prime mover carriage **200** interconnected in an operational position. In FIG. **31**, the bayonet collar **300** has been rotated until each of the pegs **160** has been seated in a small recess **320** in the anterior wall **318** at the closed end of a slot **310**. (The slot **310** and its elements are better seen in FIGS. **18–21**, for example.) In this position, the abutting surface **162** of the outer shell **152** of the drive shaft carriage **150** is pressed against the abutting surface **214** of the prime mover housing **210**. In a preferred embodiment, the pegs **160** are formed of a resilient material, such as a resilient plastic or a metal. When the pegs **160** of the drive shaft carriage **150** slide along the anterior walls **318** of the slots **310**, the free end of each peg **160** may deflect slightly proximally with respect to the other end, which is attached to the outer shell **152** of the drive shaft carriage. As a result, the pegs **160** act as leaf springs, urging the bayonet collar **300** distally and pressing the abutting surfaces **162** and **214** against one another.

In FIG. **31**, the central extension of the drive shaft socket **180** is more fully received within the guide wire lumen of the prime mover shaft **230**. This ensures that the guide wire lumen of the drive shaft **60** is in fluid communication with the guide wire lumen of the prime mover shaft **230** while minimizing leakage at this junction. In addition, the fluid drainage outlets **224** in the guiding sleeve **220** are in fluid communication with the proximal fluid drainage outlets **158** in the outer shell **152** of the drive shaft carriage. Preferably, the fluid drainage outlets **224** of the guiding sleeve **220** open into a shallow circumferential groove **226** (better seen in FIGS. **36–39**, for example) in the guiding sleeve **220**. This shallow circumferential groove **226** maintains fluid communication between the fluid drainage outlets **224** and **158** so long as the fluid drainage outlets **224** of the guiding sleeve

220 are longitudinally aligned with the proximal fluid drainage outlets **158** of the outer shell **152**. The shallow circumferential groove **226** eliminates the need for the fluid drainage outlets **224** of the guiding sleeve **220** to be axially aligned with the proximal fluid drainage outlets **158** of the outer shell **152** to ensure proper fluid drainage from the guiding sleeve **220**.

As can be seen in FIG. **31**, the free ends of the flexible pins **332** of the prime mover coupling **330** have been received within the drive shaft socket **180**. The pins **332** of the prime mover coupling **330** do not contact the interior engagement surface of the drive shaft socket **180**. Desirably, the pins **332** do not contact any part of the interior surface of the drive shaft socket **180**. More importantly, the prime mover coupling **330** should not effectively engage an interior surface of the drive shaft socket **180** when the prime mover coupling **330** is not rotating.

FIG. **32** is similar to FIG. **31**, but the rotational atherectomy device has been advanced over a guide wire **104**. In particular, the guide wire **104** extends through the guide wire lumen of the drive shaft **60**, the guide wire lumen of the prime mover shaft **230**, the lumen of the short collar **276**, and the lumen of the proximal inner telescoping tube **290**.

FIG. **33** is a longitudinal cross sectional view similar to FIG. **32**, but showing the interconnected drive shaft carriage **150** and prime mover carriage **200** being moved proximally to a position where the drive shaft carriage **150** is disconnected from the tubular housing **110** of the exchangeable drive shaft cartridge **80**. In particular, the interconnected carriages **150** and **200** have been moved proximally so that the proximal ends of the resilient tabs **114** have deflected radially outwardly and the shoulders **116** of the tabs are sliding over the top of the flange **154** carried by the outer shell **152** of the drive shaft carriage.

FIG. **34** is a longitudinal cross sectional view similar to FIG. **33** showing the drive shaft carriage **150** disconnected from the tubular housing **110** of the exchangeable drive shaft cartridge **80** and moved proximally away from the tubular housing **110**. FIG. **35** is similar to FIG. **34**, but shows the device in a perspective cross sectional view. This perspective view is advantageous in that it affords a better view of many of the components, particularly the turbine wheel **250** and the rotor **260** of the optical tachometer.

FIGS. **36–39** schematically illustrate operation of one embodiment of a prime mover coupling **330** of the invention. FIG. **36** is an enlarged view of the outlined section of FIG. **34** when the prime mover and the prime mover coupling **330** are not rotating while FIGS. **37–39** schematically show what happens upon increasingly rapid rotation of the prime mover and the prime mover coupling **330**.

The prime mover coupling **330** of FIGS. **36–39** generally comprises a coupling base **340** and at least two flexible pins **332**. Desirably, there are at least six flexible pins and the pins are spaced equiangularly about an axis of the coupling base. Preferably, these pins **332** are formed of a superelastic material, e.g., nitinol, an alloy of nickel and titanium which is well known and widely used in the medical device industry. Each flexible pin **332** is anchored to the coupling base **340** adjacent one end and has a free end which is free to deflect radially outwardly to effectively engage the drive shaft socket **180** when the prime mover is rotated. In the embodiment of FIGS. **26–29**, the coupling base **340** includes a plurality of proximally extending bores **342**. Each bore **342** receives the anchored end portion of a flexible pin **332** and the pins may be press-fitted in place.

An intermediate portion of each flexible pin **332** is received in a counterbore **344** in the coupling base **340**. The inner diameter of each counterbore **344** is greater than the outer diameter of the pin received therein. As explained more fully below, the wall **346** of each counterbore **344** serves as an abutment to limit outward deflection of an intermediate point along the length of the flexible pin **332**.

The coupling base **340** can be formed of any suitable material; stainless steel has been found to work well. If so desired, the flexible pins **332** may be integrally formed with the coupling base **340**. In this case, the coupling base should also be formed of a superelastic material, e.g., nitinol. In the illustrated embodiment, the coupling base **340** is attached to the distal end portion of the outer tubular portion **240** of the prime mover shaft **230**. If so desired, though, the coupling base **340** can be integrally formed with the prime mover shaft **230**. To further reduce the number of components, the prime mover shaft **230**, the coupling base **340** and the flexible pins **332** all can be integrally formed as a single component.

In the embodiment shown in FIGS. **36–39**, each flexible pin **332** is anchored adjacent a proximal end to the coupling base **340** and has a distal end which is free to deflect radially outwardly to engage the interior engagement surface **184** of the engagement ring **182** of the drive shaft socket **180** when the prime mover is rotated. It should be understood, though, that the flexible pins **332** can be oriented differently so that their distal ends are anchored to the coupling base **340** and the proximal ends of the pins can be free to deflect into engagement with the interior surface of the drive shaft socket **180**. Such an embodiment is less desirable, though, because it would require a much longer engagement ring **182**.

The precise dimensions of the components of the prime mover coupling **330** and the drive shaft socket **180** can be varied as necessary to achieve the desired performance characteristics, e.g., the rotational speed at which the flexible pins **332** of the prime mover coupling **330** effectively engage the drive shaft socket **180** and the torque which is conveyed from the prime mover coupling **330** to the drive shaft socket **180**. One embodiment has been found useful for use in connection with a rotational atherectomy device which is intended to be operated in a broad range of operational speeds, e.g., from about 20,000 to about 200,000 revolutions per minute (rpm). In this exemplary embodiment, the flexible pins **332** are formed of round nitinol wire having a diameter of about 0.77 mm (about 0.03 inches). The pins **332** are about 13 mm long, with about 2.5 mm being press fitted in the bore **342** in the coupling base **340**, about 4.5 mm being received in the counterbore **344** in the coupling base, and about 6 mm extending distally beyond the distal end of the counterbore **344**. The distal ends of the flexible pins **332** are beveled, as shown. There are six such pins spaced equiangularly about the axis of the coupling base and the distance between the axes of diametrically opposed pins is about 3.9 mm. The counterbores **344** in the coupling base each have a diameter of about 0.9 mm. The inner tubular portion **242** of the prime mover shaft **230** has an inner diameter of about 1.07 mm.

The drive shaft socket **180** of this embodiment has an engagement ring **182** which extends proximally from the proximally oriented face **188** of the socket about 3.0 mm and has an inner diameter of about 4.8 mm. The engagement ring **182** has a smooth interior engagement surface **184**. The central extension **196** of the drive shaft socket **180** has an outer diameter of about 0.9 mm and extends proximally of the proximally oriented face **188** of the socket about 2.5 mm.

When the prime mover carriage **200** and drive shaft carriage **150** are assembled in their operational position illustrated in FIG. **36**, the distal end of the coupling base **340** is spaced about 3.5 mm from the proximal end of the engagement ring **182** so that about 2.5 mm at the distal end of each pin is received within the drive shaft socket **180**. The clearance between the flexible pins **332** and the interior engagement surface **184** of the engagement ring **182** is about 0.065 mm. About 0.5 mm of the central extension **196** of the drive shaft socket **180** is received within the inner tubular portion **242** of the prime mover shaft. Since the inner diameter of the inner tubular portion **242** of the prime mover shaft is slightly larger than the outer diameter of the central extension **196** of the drive shaft socket **180**, there should be a small clearance between these two parts.

When the prime mover is rotated, the free ends of the flexible pins **332** will deflect radially outwardly. FIG. **37** illustrates the beveled distal ends of the flexible pins **332** coming into contact with the interior engagement surface **184** of the engagement ring **182**. In the specific embodiment detailed immediately above, one would expect to see such deflection at lower rotational speeds of the prime mover, e.g., about 18,000 to about 22,000 rpm.

FIG. **38** illustrates the pins **332** deflected further, with an intermediate point along the length of each flexible pin **332** contacting the distal end of the wall of the counterbore **344**. In the specific embodiment detailed above, one would expect the flexible pins **332** to deflect into contact with the walls of the counterbores **344** at rotational speeds of about 100,000 rpm. The wall **346** of each counterbore **344** serves as an abutment to limit outward deflection of the intermediate point of the flexible pin **332**. Support provided by this abutment helps to achieve appropriate frictional engagement between the pins **332** and the drive shaft socket **180** throughout a relatively wide range of rotational speeds of the prime mover.

FIG. **39** illustrates how the flexible pins **332** deflect when the prime mover is rotated at higher speeds. At these speeds, a significant length of a distal end portion of each pin **332** contacts the interior engagement surface **184** of the engagement ring **182**, thereby providing maximum frictional contact between the pins and the interior surface of the drive shaft socket **180**. This assures that upon sufficiently rapid rotation of the prime mover, the pins **332** of the prime mover coupling **330** will effectively engage the interior surface of the drive shaft socket **180** so the drive shaft socket **180** and the drive shaft **60** will rotate together with the prime mover coupling **330** and the prime mover. In the specific embodiment detailed above, one would expect to see the pins **332** to deflect as shown in FIG. **39** at rotational speeds in excess of about 180,000 rpm. It should be understood, though, that very reliable frictional engagement between the pins **332** of the prime mover coupling **330** and the drive shaft socket **180** takes place at much lower rotational speeds.

In the specific embodiment detailed above reliable frictional engagement between the pins of the prime mover coupling and the drive shaft socket usually is achieved at rotational speeds in the range of 35,000 to 40,000 rpm. By changing dimensions of the elements of the prime mover coupling and the drive shaft socket, one can readily vary the range of operational speeds throughout which one can achieve very reliable frictional engagement between the pins **332** and the socket **180**. For example, using flexible pins **332** of a smaller diameter and/or a longer length will decrease the rotational speeds necessary to achieve very reliable frictional engagement between the pins and the drive shaft socket. The same result also can be achieved by reducing the clearance between the flexible pins **332** and the engagement ring **182** of the drive shaft socket.

When the prime mover is no longer rotated, the flexible pins **332** of the prime mover coupling **330** will tend to resiliently regain their original, non-deflected state, as shown in FIG. **36**, thereby disconnecting the prime mover coupling **330** from the drive shaft socket **180**. This disconnects the drive shaft **60** from the prime mover so the exchangeable drive shaft cartridge **80** can be replaced by another exchangeable drive shaft cartridge having a tissue removal implement of a different size or a different design.

Deflection of the pins **332** radially outwardly upon rotation of the prime mover can be viewed as radial expansion of the prime mover coupling **330**. When the prime mover stops rotating and the flexible pins **332** regain their original shape, the prime mover coupling **330** regains a radially reduced dimension, thereby disconnecting the drive shaft socket **180** and the drive shaft **60** from the prime mover.

FIGS. **40** and **41** illustrate an alternative embodiment of the coupling base **340** shown in FIGS. **36–39**. In FIGS. **36–39**, each pin is received in a separate counterbore **344**. In this embodiment, the wall **346** of each counterbore **344** serves as a separate abutment which limits outward deflection of an intermediate point along the length of the pin received therein. In FIGS. **40** and **41**, however, these individual counterbores are all replaced with a single annular recess **344'** having a single annular wall **346'**, which extends longitudinally distally from the coupling base **340** and is spaced radially outwardly from each of the flexible pins **332** when the coupling base is not rotated.

FIG. **42** is an isolational view of the prime mover carriage **200** shown in FIG. **26**. FIGS. **43** and **44** illustrate how the flexible pins **332** of the prime mover coupling **330** can rub against an interior surface of the guiding sleeve **220** of the prime mover carriage **200** upon rapid rotation of the prime mover when the prime mover carriage **200** is not interconnected with the drive shaft carriage **150**. Potentially, this could damage either the pins **332** or the guiding sleeve **220**.

FIGS. **45–50** illustrate a preferred embodiment wherein the prime mover carriage **200** further comprises a coupling shield which restricts radial expansion of the prime mover coupling upon rapid rotation of the prime mover when the prime mover coupling **330** is not properly received within the drive shaft socket **180**. This coupling shield comprises an annular collar **350** which can surround a length of the flexible pins **332**.

The annular collar **350** is carried by the coupling base **340** of the prime mover coupling and should be free to slide longitudinally along the coupling base. The coupling shield is desirably biased distally into a protective position around the flexible pins **332**, such as by means of a compression spring **352** carried by the coupling base **340** between a rim **348** of the coupling base and a proximal face of the annular collar **350**. The coupling base **340** and the annular collar **350** shown in the drawings are fitted together in a tongue-in-groove relationship to guide the collar **350** generally longitudinally along the coupling base **340** and limit rotation of the collar **350** with respect to the base **340**. In the illustrated embodiment, the coupling base **340** includes a pair of short alignment pegs **354** which extend radially outwardly from the coupling base and are slidably received in longitudinal slots **356** in the annular collar **350**. It should be noted, however, that there should be no deleterious consequences if the annular collar **350** is permitted to rotate with respect to the coupling base **340**. Furthermore, permitting the collar **350** to rotate with respect to the coupling base **340** may reduce the cost of the prime mover coupling and simplify its assembly.

The coupling shield will restrict outward deflection of the free distal ends of the flexible pins **332** even if an operator accidentally activates the prime mover when the prime mover coupling **330** is not properly received within the drive shaft socket **180**. Upon rapid rotation of the prime mover, the deflecting pins **332** will abut the annular collar **350**, as shown in FIG. **47**, instead of rubbing against the interior of the guiding sleeve **320**. Since the annular collar **350** is rotated together with the coupling base **340** and the pins **332**, it will not be damaged by the pins.

FIGS. **48–50** illustrate how the distal end portions of the flexible pins **332** can be properly received within the drive shaft socket **180** when the drive shaft carriage **150** and the prime mover carriage **200** are connected to one another. The annular collar **350** presents a generally annular distal face which is sized to abut the drive shaft socket **180**. When the prime mover coupling **330** is moved toward the drive shaft socket **180**, the drive shaft socket **180** will move the annular collar **350** proximally away from the distal ends of the flexible pins **332** to permit the distal end portions of the pins **332** to be properly received within the socket **180**. When the prime mover is rotated, the flexible pins **332** can deflect radially outwardly into frictional engagement with the interior surface of the drive shaft socket **180**, as shown in FIG. **50**.

FIGS. **51–53** illustrate an alternative embodiment of a prime mover coupling **530** in accordance with the present invention. Elements in FIGS. **51–53** bear the same reference numbers as the numbers used for like elements of the embodiment shown in FIGS. **34**, **36** and **39**, for example. In this alternative embodiment, the prime mover coupling comprises an elastomeric, radially expandable tube **532**. The distal end portion of the expandable tube **532** is connected to the prime mover shaft **230** and the proximal end of the tube **532** is free to expand radially outwardly to engage the interior engagement surface **184** of the drive shaft socket **180** when the prime mover is rotated. In FIGS. **51–53**, the expandable tube **532** is held in place about the prime mover shaft **230** by a fixation ring **540**, but the tube **532** can instead be glued or vulcanized to the shaft **230**. The tube can be formed of any suitable elastomeric material; rubber and silicone compounds are believed to be suitable. It is also worth noting that the prime mover shaft **230** shown in these drawings is integrally formed as a single component rather than being formed of inner and outer tubular portions as illustrated in the previous drawings.

FIGS. **54** and **55** illustrate a modification of the embodiment of FIGS. **51–53**. In this embodiment, the prime mover coupling **630** includes a different radially expandable tube **632**. The radially expandable tube **532** in FIGS. **51–53** is substantially uniform along its length, but the distal portion **634** of the tube **632** in FIGS. **54** and **55** is thicker than its intermediate portion **636**. The intermediate portion **636** of the tube **632** extends between the thicker distal portion **634** and the proximal portion **638**, which is attached to the inner tubular portion **242** of the prime mover shaft. Both the distal **634** and intermediate **636** portions of the expandable tube **632** are free to expand radially outwardly. If the material forming the expandable tube **632** is uniform along the length of the tube, the distal portion **634** will have a greater mass per unit length than the intermediate portion **636**. The same objective can be achieved by varying the density of the material of the tube along its length without changing the dimensions of the tube.

In FIGS. **54** and **55**, the proximal portion **638** of the expandable tube **632** is attached to the inner tubular portion **242** of the prime mover shaft by an adhesive. The proximal portion **638** of the tube **632** may have a smaller inner diameter than the rest of the tube **632** so there is some clearance between the inner tubular portion **242** of the prime mover shaft and the intermediate **636** and distal **634** portions of the tube.

FIGS. **56** and **57** show yet another alternative embodiment of a prime mover coupling in accordance with the invention. This prime mover coupling **730** includes a coupling base **740** and at least two flyweights **732** carried by the coupling base. Each flyweight **732** should be free to move radially outwardly to engage the interior engagement surface **184** of the engagement ring **182** of the drive shaft socket **180** when the prime mover is rotated. In the illustrated embodiment, each flyweight is slidably received in a radially extending bore in the coupling base. The coupling base **740** also includes a circumferential stop **746** for limiting outward movement of the flyweights. This stop **746** has holes aligned with the bores in the coupling base **740** to permit an outer portion of the flyweights **732** to pass therethrough. The flyweights **732** may be biased inwardly with respect to the circumferential stop **746** by compression springs **742** or the like. In the embodiment shown in FIGS. **56** and **57**, the coupling base **740** of the prime mover coupling and the prime mover shaft **230** are integrally formed as a single component.

FIGS. **58** and **59** show a modified version of a drive shaft socket which is useful in connection with a prime mover coupling **730** employing flyweights **732**. In particular, the interior engagement surface **754** of the engagement ring **752** of the drive shaft socket **180** includes recesses **756** for engaging the flyweights **752**. As illustrated, these recesses may simply extend radially through the engagement ring **752**.

FIG. **60** is a longitudinal cross sectional view taken along line **60—60** of FIG. **34** and illustrating a flexible fluid supply tubing **360** attached to the exchangeable drive shaft cartridge **80**. This flexible fluid supply tubing **360** is in fluid communication with the fluid-receiving recess **144** of the distal bulkhead **140**. From the fluid-receiving recess **144**, fluid may flow distally into the lumen of the catheter **70** and proximally into the lumen of the longitudinally extendable tube **100**. As detailed above, the longitudinally extendable tube **100** is comprised of inner **90** and outer **82** telescoping tubes. The lumens of the outer **82** and inner **90** telescoping tubes and the lumen of the catheter **70** together define the drive shaft lumen **85** within which a majority of the length of the drive shaft is received.

Fluid supplied to the drive shaft lumen **85** will help reduce friction between the drive shaft **60** and the walls of the telescoping tubes **82**, **90** and the catheter **70**.

In the assembled device, the central extension **196** of the drive shaft socket **180** is received within the distal end of the guide wire lumen **236** of the prime mover shaft **230**. This establishes fluid communication between the guide wire lumen of the drive shaft **60** and the guide wire lumen **236** of the prime mover shaft while minimizing leakage at this junction. The helically wound coil **238** disposed within the guide wire lumen **236** of the prime mover shaft rotates with the prime mover and is desirably oriented such that it will urge fluid proximally when the prime mover is rotated. The proximal end of the guide wire lumen **236** is in fluid communication with the short collar **276** and the proximal inner telescoping tube **290**. A small gap is provided between the proximal end of the prime mover shaft **230** and the short collar **276** so some fluid may drain through the fluid outlet **278** in the proximal bulkhead **270**.

One end of the flexible fluid supply tubing **360** communicates with an external fluid supply (not shown) while the other end of the tubing **360** is attached to the exchangeable drive shaft cartridge **80**. Desirably, the fluid supply tubing **360** is attached to the exchangeable drive shaft cartridge **80** distally of at least one of the telescoping tubes **82, 90**. Preferably, it is connected distally of both of the telescoping tubes **82, 90** and proximally of the catheter **70**. In the illustrated embodiment, the fluid supply tubing **360** is attached to a metal tubing **362** carried by the distal bulkhead **140**. The metal tubing **362** communicates with the fluid-receiving recess **144** in the bulkhead through the passageway **142**. The distal bulkhead **140** is disposed between and operatively connects the inner telescoping tube **90** and the proximal end portion **72** of the catheter **70**. Positioning the distal bulkhead **140** distally of the inner telescoping tube **90** assures that the fluid supply tubing **360** is attached to the exchangeable drive shaft cartridge **80** adjacent the distal end of the longitudinally extendable tube **100** and spaced distally from the drive shaft socket **180**.

As noted above, the distal bulkhead **140** includes a narrow opening **145** which defines a reduced diameter segment of the drive shaft lumen **85**. As better seen in the enlarged view of FIG. **61**, the flexible drive shaft **60** passes through this narrow opening **145**. Preferably, sufficient clearance exists between the drive shaft and the interior of the narrow opening **145** to permit a restricted flow of fluid proximally along the drive shaft lumen.

FIG. **62** illustrates a preferred embodiment of a device of the invention wherein a thin-walled heat shrinkable tubing **67** has been shrunk onto a length of the intermediate portion **64** of the flexible drive shaft **60**. This tubing desirably extends distally from the distal end of the inner tubular shaft portion **194** of the socket **180** to a point located distally of the narrow opening **145** even when the longitudinally extendable tube **100** is at its maximum length. Preferably, the tubing **67** extends distally beyond the location where the fluid supply tubing delivers fluid to the drive shaft lumen, and optimally extends distally into the proximal end portion of the catheter. In one embodiment which has been found to work well, the tubing **67** extends distally from the distal end of the inner tubular shaft portion **194** of the socket **180** for a length of at least about 160 mm, and preferably for a length of about 200 mm. This embodiment uses a polyester heat shrinkable tubing manufactured with an average inner diameter of 28 mils and an average wall thickness of 0.4 mils, such as is commercially available from Advanced Polymers, Inc. of Salem, N.H., USA as item 028040BHGS.

It should be noted that FIGS. **61** and **62** are schematic and are not truly to scale. By way of example, in the embodiment of FIG. **62**, one may use a flexible drive shaft **60** having an outer diameter of about 0.66 mm without the heat shrinkable tubing **67** and acquiring an outer diameter of about 0.69 mm after the tubing **67** has been heat shrunk on the drive shaft **60**. In this illustrative embodiment, the narrow opening **145** has a diameter of about 0.80 mm and extends for about 3 mm. Fluid is supplied to the fluid-receiving recess **144**, which is positioned distally of the narrow opening **145**. As a result, more fluid will flow distally into the lumen of the catheter **70** than proximally into the lumen of the longitudinally extendable tube **100**. As noted above, FIGS. **61** and **62** are not truly to scale and in the specific embodiment described above the fluid-receiving recess **144** has a diameter of about 1.1 mm.

Distally of the distal end of the heat shrinkable tubing **67**, the fluid will pass between wire turns of the drive shaft **60** into the guide wire lumen of the drive shaft, thereby reducing friction between the drive shaft **60** and the guide wire **104**. When the drive shaft **60** is rotated, the drive shaft will actively pump this fluid proximally along the guide wire lumen of the drive shaft. This pumping effect can be achieved by appropriately orienting the wire turns of the drive shaft and rotating the drive shaft in the appropriate direction.

In previous systems, a centrifugal pump rotated by the prime mover pumps fluid distally into a space defined by the telescoping tubes and then into the catheter. This generates significant pressure in that space, which will tend to urge the turbine block proximally. In order to move the tissue removal implement distally, the operator must apply significant manual force to the turbine block just to overcome this back pressure. This makes distal movement of the tissue removal implement more difficult and reduces the operator's tactile ability to gauge the force with which he is pressing the tissue removal implement against the stenosis.

One advantage of the illustrated invention is that the pressure of fluid within the longitudinally extendable tube **100** (telescoping tubes **82, 90**) is reduced without compromising the flow of fluid distally through the catheter **70**. As a result, the back pressure against the interconnected carriages **150, 200** is significantly reduced and the operator's tactile ability to gauge the force with which he is pressing the tissue removal implement against the stenosis is enhanced.

At the proximal end of the longitudinally extendable tube **100**, fluid will flow proximally within the guide wire lumen of the proximal portion **62** of the drive shaft **60**. Fluid also will flow proximally between the central core **170** of the drive shaft carriage **150** and the inner tubular shaft portion **194** of the drive shaft socket **180**. The fluid flowing between the core **170** and the inner tubular shaft portion **194** will reduce friction between these two components and effectively serve as a fluid bearing, providing distal support to the tubular shaft of the drive shaft socket. In one useful embodiment, the inner diameter of this portion of the central core **170** is about 1.1 mm and the outer diameter of the inner tubular shaft portion **194** is about 1.07 mm. The fluid passing between the central core **170** and the tubular shaft **190** can drain out of the drive shaft carriage **150** through drainage outlets **176** passing through the central core **170** and the outer shell **152**.

Most of the fluid which flows proximally within the guide wire lumen of the proximal portion **62** of the drive shaft **60** will tend to flow into the guide wire lumen **236** of the prime mover shaft **230**. Some fluid may escape into the space surrounded by the guiding sleeve **220**. To limit access of fluid to the distal bearing **252**, the guiding sleeve **220** includes fluid drainage ports **224** which communicate with the fluid drainage ports **158** of the outer shell **152**.

In one preferred embodiment, the coupling base **340** includes a dynamic seal **366** for urging fluid away from the distal bearing **252**. As best seen in the enlarged view of FIG. **63**, this dynamic seal is comprised of a series of generally frustoconical flanges **358** spaced along the proximal portion of the coupling base **340**. Preferably, these frustoconical flanges **358** are formed integrally with the coupling base **340** and are oriented to flare outwardly in a distal direction. When the coupling base is rotated, these frustoconical flanges **358** will tend to urge fluid distally away from the distal bearing **252**. As a result, each of the flanges acts as a barrier which centrifugally urges fluid distally in response to rotation of the prime mover.

In one embodiment which has been found to work well, there are five frustoconical flanges **358** in the dynamic seal

366. Each flange has a distal face which has a depth of about 0.4 mm. Each flange has a length of about 0.9 mm from the distal face of one flange to the distal face of the next flange. The frustoconical surface of each flange forms an angle of about 60° with respect to the distal face of the adjacent flange. There is a clearance of about 0.025 mm between the short cylindrical surface of each flange and the interior surface of the guiding sleeve **220**.

In addition to the fluid drainage outlets already mentioned above, additional fluid drainage outlets can be provided. For example, the illustrated embodiment includes drainage outlets at the proximal and distal ends of the generally tubular housing **110** of the exchangeable drive shaft cartridge **80** to drain any fluid escaping into the housing from the longitudinally extendable tube **100**.

FIG. **64** is a broken-away, longitudinal cross sectional view of the proximal portion **12** of the handle **10** and the proximal end of the prime mover carriage **200**. As noted above, two moveable proximal telescoping tubes **280** and **290** are secured to and extend proximally from the proximal bulkhead **270** of the prime mover carriage **200**. These proximal telescoping tubes **280** and **290** are secured to the bulkhead **270** by the proximal cap **272** and the ring **234**. The proximal outer telescoping tube **280** and the proximal inner telescoping tube **290** are moveable together with the prime mover carriage **200**. As shown in the drawings, the proximal inner telescoping tube **290** has an outer diameter substantially smaller than the inner diameter of the proximal outer telescoping tube **280** so that an annular space **282** is formed between these two proximal telescoping tubes.

The moveable proximal telescoping tubes **280** and **290** are slidably received in the proximal portion **12** of the handle **10**. In the illustrated embodiment, a stationary telescoping tube **370** is carried by the proximal portion **12** of the handle. This stationary telescoping tube **370** is disposed within a cylindrical recess in the proximal portion **12** of the handle. The stationary telescoping tube **370** is secured proximally to the proximal portion **12** of the handle. The stationary telescoping tube **370** has an outer diameter which is substantially smaller than the diameter of the cylindrical recess of the proximal portion **12** of the handle. As a result, there is an annular space **372** defined between the outer surface of the stationary telescoping tube **370** and the inner surface of the cylindrical recess.

The proximal outer telescoping tube **280** is slidably received in the annular space **372**. The proximal inner telescoping tube **290** is slidably received within the stationary telescoping tube **370**. As a consequence, when the prime mover carriage **200** is moved longitudinally with respect to the proximal portion **12** of the handle, the proximal telescoping tubes **280** and **290** will move longitudinally with respect to the stationary telescoping tube **370**. Because the stationary telescoping tube **370** and both proximal telescoping tubes **280** and **290** desirably are round, the prime mover carriage **200** and the proximal telescoping tubes **280** and **290** may be rotated with respect to the proximal portion **12** of the handle.

To prevent the proximal telescoping tubes **280** and **290** from being removed from the proximal portion **12** of the handle, distal movement of the proximal outer telescoping tube **280** is limited by a pair of stops, one stop **288** being carried adjacent the proximal end of the proximal outer telescoping tube **280** and the other stop **374** being carried adjacent the distal end of the proximal portion **12** of the handle **10**. To limit friction between the proximal outer telescoping tube **280** and the proximal portion **12** of the handle, these stops **288** and **374** may be formed of a low friction material such as polytetrafluoroethylene.

FIG. **64** also illustrates one possible manner of attaching the proximal portion **12** and intermediate portion **14** of the handle **10** to one another. In this embodiment, the intermediate portion **14** of the handle is formed of an elongate tube or rod. This tube may be press fitted, glued or otherwise secured within a mating recess in the proximal portion **12** of the handle. If so desired, the proximal portion **12** and intermediate portion **14** of the handle **10** could instead be integrally formed as a single component. The proximal portion **12** of the handle **10** optimally includes a detachable leg **16**, discussed in more detail below in connection with FIG. **67**.

If so desired, the proximal portion **12** of the handle **10** may also include a carriage brake to lock the prime mover carriage **200** in a desired position. FIG. **64** shows this carriage brake in a longitudinal cross section at the distal end of the proximal portion **12** of the handle **10** while FIGS. **65** and **66** show the carriage brake in transverse cross section. The carriage brake generally includes a vertically moveable elongated braking shoe **380** and an actuating cam **382**. A manually graspable actuating knob **390** is attached to the actuating cam **382** to enable a user to rotate the cam to engage and disengage the carriage brake. A distal plate **392** helps keep the braking shoe **380** and actuating cam **382** in place adjacent the distal end of the proximal portion **12** of the handle **10**.

FIGS. **65** is a transverse cross sectional view taken along line **65—65** in FIG. **64** and illustrating the carriage brake in an unlocked position while FIG. **66** is a cross sectional view similar to FIG. **65**, but showing the carriage brake in a locked position. As can be seen in these figures, the actuating cam **382** desirably has an unlocking recess **384** and a locking recess **386**, with the locking recess being shallower than the unlocking recess. As shown in FIG. **65**, when the lower end of the elongated braking shoe **380** is received in the unlocking recess of the actuating cam, the upper end of the elongated braking shoe **380** will be spaced away from the proximal outer telescoping tube **280**. This permits the proximal outer telescoping tube **280** to move freely. As shown in FIG. **66**, when the lower end of the elongated braking shoe **380** is received in the shallower locking recess of the actuating cam, the upper end of the elongated braking shoe **380** will be urged against the outer surface of the proximal outer telescoping tube **280**. This will effectively lock the proximal outer telescoping tube **280** in place with respect to the proximal portion **12** of the handle.

FIG. **67** is a transverse cross sectional view taken along line **67—67** in FIG. **64** and illustrating how a removable leg **16** is clamped onto the proximal portion **12** of the handle. As seen in FIG. **1**, for example, there is a similar leg **16** clamped onto the distal portion **20** of the handle, as well. The legs help stabilize the handle **10** when an operator is placing an exchangeable drive shaft cartridge **80** in the groove **24** of the distal portion **20** of the handle **10** or removing an exchangeable drive shaft cartridge from the distal portion of the handle. The detachable legs **16**, however, provide an operator with the ability to remove the legs during a procedure so he can manually grasp the distal portion **20** of the handle **10** with one hand while moving the interconnected carriages **150** and **200** with the other hand. Some operators or their assistants may also find it convenient to manually grasp the proximal portion **12** of the handle **10** when actuating the guide wire clamp override mechanism using the override button **410**.

The legs **16** can be attached to the handle **10** using any one of a variety of disengageable mechanical linkages. A number of different mechanical linkages are described in U.S. patent application Ser. No. 08/792,102, filed 31 Jan. 1997, the teachings of which are incorporated herein by reference. In the illustrated embodiment, the legs **16** each comprise a horizontal foot and an upwardly extending clamp **400** for securing the leg **16** to the handle. The clamp has two pairs of upwardly extending arms sized and shaped to interlock with recesses **402** in the handle **10**. One pair of such recesses **402** may be provided in each of the proximal portion **12** and distal portion **20** of the handle **10**, permitting the legs **16** to be snapped on and off of the handle **10**. Desirably, the legs **16** are interchangeable. If so desired, the horizontal foot of the leg **16** may also be provided with one or more pads **404**.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made therein without departing from the spirit of the invention and the scope of the appended claims.

What is claimed is:

1. A rotational atherectomy device comprising:

a. an exchangeable drive shaft cartridge comprising a rotatable drive shaft socket carried by a drive shaft carriage; a longitudinally extendable tube extending distally from the drive shaft carriage; an elongated catheter having a proximal end portion which is operatively connected to a distal end portion of the longitudinally extendable tube; and a rotatable flexible drive shaft having proximal, intermediate and distal portions, the proximal portion being attached to the drive shaft socket, the intermediate portion being disposed primarily within the tube and the catheter, and the distal portion extending distally from the catheter and having a tissue removal implement;

b. a rotatable, radially expandable prime mover coupling connected to a prime mover for rotation therewith, the prime mover being carried by a prime mover carriage and the prime mover coupling including a radially expandable portion;

the drive shaft socket being sized to receive a length of the radially expandable portion of the prime mover coupling therein such that the radially expandable portion of the prime mover coupling does not effectively engage an interior surface of the drive shaft socket when the coupling is not rotating, but the radially expandable portion of the prime mover coupling radially expands to effectively engage the socket upon sufficiently rapid rotation of the prime mover, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover,

whereby when the prime mover is not rotating, the drive shaft is disconnected from the prime mover, thereby permitting the exchangeable drive shaft cartridge to be replaced by another exchangeable drive shaft cartridge.

2. The rotational atherectomy device of claim **1** wherein the radially expandable portion of the coupling resiliently regains a radially reduced dimension when it is not rotated, thereby disconnecting the drive shaft from the prime mover.

3. The rotational atherectomy device of claim **1** wherein the radially expandable portion of the prime mover coupling does not contact the interior surface of the drive shaft socket when the coupling is not rotating.

4. The rotational atherectomy device of claim **1** wherein the drive shaft socket includes a proximally extending engagement ring defining an interior engagement surface of the socket, the radially expandable portion of the coupling being adapted to radially expand into frictional engagement with the interior engagement surface of the socket in response to rotation of the prime mover shaft.

5. The rotational atherectomy device of claim **1** wherein the prime mover coupling further comprises a coupling base and the radially expandable portion of the coupling comprises at least two flexible pins, each pin being anchored adjacent one end thereof to the coupling base and having another end which is free to deflect radially outwardly to engage the drive shaft socket when the prime mover is rotated.

6. The rotational atherectomy device of claim **5** wherein the drive shaft socket includes a proximally extending engagement ring defining an interior engagement surface of the socket, the pins being adapted to deflect radially outwardly into frictional engagement with the interior engagement surface of the socket in response to rotation of the prime mover.

7. The rotational atherectomy device of claim **5** wherein the drive shaft socket includes a proximally extending engagement ring defining a generally cylindrical interior engagement surface of the socket, the pins being adapted to deflect radially outwardly into frictional engagement with the interior engagement surface of the socket in response to rotation of the prime mover.

8. The rotational atherectomy device of claim **5** wherein said pins are spaced equiangularly about an axis of the coupling base.

9. The rotational atherectomy device of claim **5** wherein there are at least six of said pins.

10. The rotational atherectomy device of claim **5** wherein each of the pins is formed of a superelastic material.

11. The rotational atherectomy device of claim **10** wherein said superelastic material is nitinol.

12. The rotational atherectomy device of claim **5** wherein an intermediate portion of each pin is received in a counterbore in the coupling base, each counterbore having an inner diameter greater than the outer diameter of the pin received therein.

13. The rotational atherectomy device of claim **5** wherein the coupling base includes at least one abutment spaced radially outwardly from each pin when the coupling base is not rotated and limiting outward deflection of an intermediate point along the length of the pin when the prime mover is rotated.

14. The rotational atherectomy device of claim **13** wherein the abutment comprises a single annular wall extending longitudinally from the coupling base and spaced radially outwardly from each of the pins when the coupling base is not rotated.

15. The rotational atherectomy device of claim **5** wherein the pins are integrally formed with the coupling base.

16. The rotational atherectomy device of claim **5** wherein the coupling base is integrally formed with a shaft of the prime mover.

17. The rotational atherectomy device of claim **5** wherein the pins, the coupling base and a shaft of the prime mover are all integrally formed.

18. The rotational atherectomy device of claim **5** wherein the prime mover carriage further comprises a coupling shield which restricts outward deflection of the free ends of the pins upon rotation of the prime mover when the free ends of the pins are not properly received within the drive shaft socket.

19. The rotational atherectomy device of claim **18** wherein the coupling shield is carried by the prime mover coupling and can be moved away from the free ends of the pins to permit the pins to be properly received within the socket so the pins can engage the drive shaft socket upon rotation of the prime mover.

20. The rotational atherectomy device of claim **1** wherein the prime mover coupling further comprises a coupling base and the radially expandable portion of the coupling comprises at least two flexible pins, each pin being anchored adjacent a proximal end to the coupling base and having a distal end which is free to deflect radially outwardly to engage an interior engagement surface of the drive shaft socket when the prime mover is rotated.

21. The rotational atherectomy device of claim **20** wherein the socket has a proximal end portion defining an interior surface, the pins being adapted to deflect radially outwardly into frictional engagement with the interior engagement surface of the socket in response to rotation of the prime mover shaft.

22. The rotational atherectomy device of claim **20** wherein said pins are spaced equiangularly about an axis of the coupling base.

23. The rotational atherectomy device of claim **20** wherein there are at least six of said pins.

24. The rotational atherectomy device of claim **20** wherein each of the pins is formed of a superelastic material.

25. The rotational atherectomy device of claim **24** wherein said superelastic material is nitinol.

26. The rotational atherectomy device of claim **20** wherein an intermediate portion of each pin is received in a counterbore in the coupling base, each counterbore having an inner diameter greater than the outer diameter of the pin received therein.

27. The rotational atherectomy device of claim **18** wherein the coupling base includes at least one abutment spaced radially outwardly from each pin when the coupling base is not rotated and limiting outward deflection of an intermediate point along the length of the pin when the prime mover is rotated.

28. The rotational atherectomy device of claim **27** wherein the abutment comprises a single annular wall extending longitudinally distally from the coupling base and spaced radially outwardly from each of the pins when the coupling base is not rotated.

29. The rotational atherectomy device of claim **20** wherein the pins are integrally formed with the coupling base.

30. The rotational atherectomy device of claim **20** wherein the coupling base is integrally formed with a shaft of the prime mover.

31. The rotational atherectomy device of claim **20** wherein the pins, the coupling base and a shaft of the prime mover are all integrally formed.

32. The rotational atherectomy device of claim **20** wherein the prime mover carriage further comprises a coupling shield which restricts outward deflection of the distal ends of the pins upon rotation of the prime mover when the distal ends of the pins are not properly received within the drive shaft socket.

33. The rotational atherectomy device of claim **32** wherein the coupling shield is carried by the base of the prime mover coupling and can be moved away from the distal ends of the pins to permit the pins to be properly received within the socket so the pins can engage the drive shaft socket upon rotation of the prime mover.

34. The rotational atherectomy device of claim **1** wherein the radially expandable portion of the prime mover coupling comprises an elastomeric, radially expandable tube, the tube being connected adjacent one end thereof to a prime mover shaft and having another end which is free to expand radially outwardly to engage the interior surface of the drive shaft socket when the prime mover is rotated.

35. The rotational atherectomy device of claim **34** wherein the radially expandable tube is connected to the prime mover shaft adjacent its proximal end and has a distal end which is free to expand radially outwardly.

36. The rotational atherectomy device of claim **35** wherein the tube has distal and intermediate portions which are both free to expand radially outwardly, the distal portion having a greater mass per unit length than the intermediate portion.

37. The rotational atherectomy device of claim **36** wherein the distal portion is thicker than the intermediate portion.

38. The rotational atherectomy device of claim **1** wherein the prime mover coupling further comprises a coupling base and the radially expandable portion of the coupling comprises at least two flyweights carried by the coupling base, each flyweight being free to move radially outwardly to engage an interior engagement surface of the drive shaft socket when the prime mover is rotated.

39. The rotational atherectomy device of claim **38** wherein each flyweight is slidably received in a radially extending bore in the coupling base, the coupling base including a circumferential stop for limiting outward movement of the flyweights.

40. The rotational atherectomy device of claim **38** wherein the interior engagement surface of the socket includes recesses for engaging the flyweights.

41. The rotational atherectomy device of claim **1** wherein the drive shaft carriage and the prime mover carriage are longitudinally moveable with respect to one another from an operational position wherein a length of the radially expandable portion of the prime mover coupling is received within the drive shaft socket to a non-operational position wherein the radially expandable portion of the prime mover coupling is withdrawn from the drive shaft socket.

42. The rotational atherectomy device of claim **41** wherein, in the operational position, the drive shaft carriage and the prime mover carriage are interconnected to move together as a unit to move the drive shaft and its tissue removal implement along a vascular lumen of a patient's body.

43. The rotational atherectomy device of claim **42** further comprising fittings associated with the drive shaft carriage and the prime mover carriage, the fittings being designed to fix the relative positions of the drive shaft socket and the prime mover coupling in the operational position.

44. The rotational atherectomy device of claim **43** wherein the fittings are connected to one another at three or more equiangularly spaced positions.

45. The rotational atherectomy device of claim **43** wherein at least one of the fittings is free to rotate with respect to the carriage with which it is associated to facilitate connection of the carriages to one another.

46. The rotational atherectomy device of claim **43** wherein the fittings comprise mating components of a bayonet joint.

47. The rotational atherectomy device of claim **1** wherein the drive shaft carriage and the prime mover carriage are provided with mating components of a bayonet joint to connect the carriages to one another.

48. The rotational atherectomy device of claim **47** wherein the mating components comprise pins and slots, the pins being carried by one of the carriages and the slots being formed in a bayonet collar carried by the other carriage.

49. The rotational atherectomy device of claim **48** wherein the bayonet collar is rotatable about the carriage which carries the bayonet collar.

50. The rotational atherectomy device of claim **47** wherein the bayonet joint connects the carriages to one another at three or more equiangularly spaced positions.

51. The rotational atherectomy device of claim **1** wherein the exchangeable drive shaft cartridge further comprises a generally tubular housing carrying the longitudinally extendable tube.

52. The rotational atherectomy device of claim **51** wherein the tubular housing of the drive shaft cartridge has a generally cylindrical outer surface.

53. The rotational atherectomy device of claim **51** wherein the longitudinally extendable tube includes outer and inner telescoping tubes, the outer telescoping tube being connected to the drive shaft carriage and the inner telescoping tube being connected to a distal end piece of the tubular housing.

54. The rotational atherectomy device of claim **53** wherein the outer telescoping tube is slidably received in an elongated annular space defined between an inner surface of the tubular housing and an outer surface of the inner telescoping tube.

55. The rotational atherectomy device of claim **54** wherein the outer telescoping tube is moveable both longitudinally and rotationally with respect to both the tubular housing and the in telescoping tube.

56. The rotational atherectomy device of claim **54** further comprising complementary fittings associated with the tubular housing and the drive shaft carriage for releasably locking the drive shaft carriage to the tubular housing when a majority of the length of the outer telescoping tube is received within the tubular housing of the drive shaft cartridge.

57. The rotational atherectomy device of claim **56** wherein the complementary fittings comprise at least one tab carried by one of the tubular housing and the drive shaft carriage and a flange carried by the other one of the tubular housing and the drive shaft carriage.

58. The rotational atherectomy device of claim **56** wherein the outer telescoping tube is free to rotate with respect to both the tubular housing and the inner telescoping tube when the drive shaft carriage is releasably locked to the tubular housing of the cartridge.

59. The rotational atherectomy device of claim **1** further comprising a handle which carries the prime mover carriage and which is adapted to releasably hold the drive shaft cartridge.

60. The rotational atherectomy device of claim **59** wherein the handle includes at least one clamp for releasably holding a generally tubular housing of the drive shaft cartridge.

61. The rotational atherectomy device of claim **59** wherein the prime mover carriage is longitudinally moveable with respect to the handle.

62. The rotational atherectomy device of claim **59** wherein the drive shaft carriage is longitudinally moveable with respect to the handle when the drive shaft cartridge is releasably held by the handle.

63. The rotational atherectomy device of claim **59** wherein the drive shaft carriage and the prime mover carriage are adapted to be interconnected for movement together as a unit longitudinally with respect to the handle.

64. The rotational atherectomy device of claim **59** wherein the drive shaft carriage and the prime mover carriage are adapted to be interconnected for movement together as a unit both longitudinally and rotationally with respect to the handle.

65. The rotational atherectomy device of claim **59** wherein an axis of the drive shaft carriage is substantially aligned with an axis of the prime mover carriage when the drive shaft cartridge is releasably held by the handle.

66. The rotational atherectomy device of claim **59** wherein the drive shaft carriage and the prime mover carriage are moveable with respect to one another longitudinally along their aligned axes from an operational position wherein a length of the radially expandable portion of the prime mover coupling is received within the drive shaft socket to a non-operational position wherein the radially expandable portion of the prime mover coupling is withdrawn from the drive shaft socket.

67. The rotational atherectomy device of claim **66** wherein the drive shaft carriage and the prime mover carriage are adapted to be interconnected for movement together as a unit longitudinally with respect to the handle along their aligned axes.

68. The rotational atherectomy device of claim **59** wherein the handle comprises a distal portion adapted to releasably hold the drive shaft cartridge, a proximal portion carrying the prime mover carriage, and an elongated rod connecting the distal and proximal portions of the handle to one another.

69. The rotational atherectomy device of claim **68** further comprising a telescoping tube slidably received in the proximal portion of the handle and having a distal end connected to the prime mover carriage.

70. The rotational atherectomy device of claim **69** wherein the elongated rod of the handle extends generally parallel to the telescoping tube connected to the prime mover carriage and is spaced therefrom a distance sufficient to permit both the drive shaft carriage and the prime mover carriage to move parallel to the elongated rod of the handle.

71. The rotational atherectomy device of claim **68** wherein the drive shaft carriage and the prime mover carriage are adapted to be interconnected for movement together as a unit longitudinally with respect to the handle.

72. The rotational atherectomy device of claim **68** wherein the drive shaft carriage and the prime mover carriage are adapted to be interconnected for movement together as a unit both longitudinally and rotationally with respect to the handle.

73. The rotational atherectomy device of claim **68** wherein the distal portion of the handle includes a pair of opposing walls defining a longitudinally extending groove for releasably holding a length of the drive shaft cartridge therein.

74. The rotational atherectomy device of claim **73** further comprising a slot in one of the opposing walls for receiving a flexible fluid supply tubing therein.

75. The rotational atherectomy device of claim **73** wherein the groove has a depth greater than an outer diameter of a tubular housing of the drive shaft cartridge, thereby limiting manual pressure on the tubular housing when a user grasps the handle around the groove.

76. The rotational atherectomy device of claim **73** wherein the distal portion of the handle includes at least one clamp for retaining the drive shaft cartridge in the groove.

77. The rotational atherectomy device of claim **76** wherein the handle includes two clamps, the clamps being spaced from one another longitudinally along the distal portion of the handle.

78. The rotational atherectomy device of claim **76** wherein the clamp is sized to releasably hold a generally tubular housing of the drive shaft cartridge.

79. The rotational atherectomy device of claim **78** wherein the groove in the distal portion of the handle has a depth greater than an outer diameter of the tubular housing of the drive shaft cartridge.

80. The rotational atherectomy device of claim **80** wherein the groove is upwardly open.

81. The rotational atherectomy device of claim **80** wherein the side walls defining the groove are sized to extend above the tubular housing to limit manual pressure on the tubular housing when a user grasps the handle around the groove.

82. The rotational atherectomy device of claim **76** wherein the clamp and the opposing walls defining the groove are all formed as a single component.

83. The rotational atherectomy device of claim **76** wherein the clamp and the distal portion of the handle are formed as a single component.

84. The rotational atherectomy device of claim **76** wherein the clamp, the opposing walls defining the groove and the distal portion of the handle are all formed as a single component.

85. The rotational atherectomy device of claim **76** wherein the clamp includes two opposing sides, one side of the clamp being integrally formed with one of the walls and the other side of the clamp being integrally formed with the other wall.

86. The rotational atherectomy device of claim **76** wherein the distal portion of the handle comprises two laterally opposed mating elements, one of the opposed walls and one side of the clamp being integrally formed with one of the mating elements, the other of the walls and another side of the clamp being integrally formed with another of the mating elements.

87. The rotational atherectomy device of claim **87** further comprising at least one leg removably interlockable with the handle.

88. The rotational atherectomy device of claim **87** wherein the leg includes a clamp sized and shaped to releasably interlock with the handle.

89. The rotational atherectomy device of claim **1** further comprising a flexible fluid supply tubing attached to the exchangeable drive shaft cartridge and in fluid communication with a drive shaft lumen of the drive shaft cartridge, the drive shaft lumen being defined by a lumen of the catheter and a lumen of the longitudinally extendable tube.

90. The rotational atherectomy device of claim **89** wherein the drive shaft lumen receives a majority of the length of the drive shaft.

91. The rotational atherectomy device of claim **89** wherein the drive shaft lumen includes a reduced inner diameter segment, the reduced inner diameter segment being positioned proximally of where the fluid supply tubing delivers fluid to the drive shaft lumen, thereby reducing flow of fluid proximally along the drive shaft lumen.

92. The rotational atherectomy device of claim **91** wherein a sufficient clearance exists between the drive shaft and the interior of the reduced inner diameter segment of the drive shaft lumen to permit a restricted flow of fluid proximally along the drive shaft lumen.

93. The rotational atherectomy device of claim **91** wherein a thin-walled tubing extends along a proximal length of an intermediate portion of the drive shaft from a distal end of a tubular shaft of the drive shaft socket to a point located distally of a proximal end of the reduced inner diameter segment of the drive shaft lumen.

94. The rotational atherectomy device of claim **93** wherein the thin-walled tubing extends distally beyond a distal end of the reduced inner diameter segment of the drive shaft lumen.

95. The rotational atherectomy device of claim **93** wherein the thin-walled tubing extends distally beyond the location where the fluid supply tubing delivers fluid to the drive shaft lumen.

96. The rotational atherectomy device of claim **93** wherein the thin-walled tubing extends distally into the proximal end portion of the catheter.

97. The rotational atherectomy device of claim **93** wherein the thin-walled tubing is a heat-shrinkable tubing.

98. The rotational atherectomy device of claim **93** wherein the thin-walled tubing is a heat-shrinkable polyester tubing.

99. The rotational atherectomy device of claim **93** wherein the thin-walled tubing extends for a length not less than about 160 mm.

100. The rotational atherectomy device of claim **89** wherein the fluid supply tubing delivers fluid from a fluid supply external the cartridge.

101. The rotational atherectomy device of claim **89** wherein the fluid supply tubing has two ends, one end being attached to the drive shaft cartridge distally of the drive shaft socket and the other end of the tubing being in fluid communication with an external fluid supply.

102. The rotational atherectomy device of claim **89** wherein the fluid supply tubing is attached to the drive shaft cartridge distally of the drive shaft socket.

103. The rotational atherectomy device of claim **89** wherein the fluid supply tubing is attached to the drive shaft cartridge distally of the drive shaft socket and proximally of the catheter.

104. The rotational atherectomy device of claim **89** wherein the fluid supply tubing is attached to the drive shaft cartridge adjacent a distal end of the longitudinally extendable tube.

105. The rotational atherectomy device of claim **89** wherein the longitudinally extendable tube includes at least two telescoping tubes.

106. The rotational atherectomy device of claim **105** wherein the fluid supply tubing is attached to the drive shaft cartridge distally of at least one of the telescoping tubes.

107. The rotational atherectomy device of claim **105** wherein the fluid supply tubing is attached to the drive shaft cartridge distally of all of the telescoping tubes.

108. The rotational atherectomy device of claim **105** wherein the fluid supply tubing is attached to the drive shaft cartridge distally of at least one of the telescoping tubes and proximally of the catheter.

109. The rotational atherectomy device of claim **105** wherein the fluid supply tubing is attached to the drive shaft cartridge primally of the catheter.

110. The rotational atherectomy device of claim **89** wherein the drive shaft comprises a helically wound coil which defines a guide wire lumen of the drive shaft, fluid supplied to the drive shaft lumen passing between wire turns of the drive shaft into the guide wire lumen.

111. The rotational atherectomy device of claim **110** wherein a generally tubular shaft of the prime mover defines a guide wire lumen which extends proximally from the guide wire lumen of the drive shaft when the radially expandable portion of the prime mover coupling is received in the drive shaft socket.

112. The rotational atherectomy device of claim **111** wherein the guide wire lumen of the drive shaft and the guide wire lumen of the prime mover shaft are aligned and in fluid communication with one another when the radially expandable portion of the prime mover coupling is received in the drive shaft socket, thereby permitting the drive shaft and the prime mover to be advanced together as a unit over the guide wire.

113. The rotational atherectomy device of claim **111** wherein the guide wire lumen of the drive shaft and the guide wire lumen of the prime mover shaft are aligned and in fluid communication with one another when the radially expandable portion of the prime mover coupling is received in the drive shaft socket, thereby permitting the drive shaft and the prime mover to be rotated together as a unit over the guide wire.

114. The rotational atherectomy device of claim **111** wherein the guide wire lumen of the drive shaft and the guide wire lumen of the prime mover shaft are aligned and in fluid communication with one another when the radially expandable portion of the prime mover coupling is received in the drive shaft socket, thereby permitting the drive shaft and the prime mover to be advanced and rotated together as a unit over the guide wire.

115. The rotational atherectomy device of claim **111** wherein the guide wire lumen of the prime mover shaft is in fluid communication with a fluid outlet located adjacent a proximal end of the prime mover shaft.

116. The rotational atherectomy device of claim **111** further comprising a helically wound coil disposed within the guide wire lumen of the prime mover shaft, the coil being rotatable together with the prime mover.

117. The rotational atherectomy device of claim **116** wherein the coil disposed within the prime mover shaft is oriented to urge fluid proximally when the prime mover is rotated.

118. The rotational atherectomy device of claim **111** wherein the drive shaft socket includes a proximally oriented face and a central extension which extends proximally from that face, the guide wire lumen of the prime mover shaft slidably receiving a proximal length of the central extension of the socket when the radially expandable portion of the prime mover coupling is received in the drive shaft socket such that the guide wire lumen of the drive shaft is in fluid communication with the guide wire lumen of the prime mover shaft.

119. The rotational atherectomy device of claim **1** wherein the prime mover coupling includes a dynamic seal for urging fluid away from a bearing supporting a shaft of the prime mover.

120. The rotational atherectomy device of claim **119** wherein the dynamic seal includes a barrier centrifugally urging fluid distally in response to rotation of the prime mover.

121. The rotational atherectomy device of claim **120** wherein the barrier comprises a generally frustoconical flange carried by a proximal portion of the prime mover coupling.

122. The rotational atherectomy device of claim **121** further comprising a plurality of such barriers spaced along the proximal portion of the prime mover coupling.

123. The rotational atherectomy device of claim **1** wherein the prime mover carriage further comprises a coupling shield which restricts radial expansion of the radially expandable portion of the prime mover coupling upon rotation of the prime mover when the radially expandable portion of the prime mover coupling is not properly received within the drive shaft socket.

124. The rotational atherectomy device of claim **123** wherein the coupling shield is carried by the prime mover coupling and can be moved away from a distal end of the coupling to permit the radially expandable portion of the coupling to be properly received within the socket so the radially expandable portion of the coupling can engage the drive shaft socket upon rotation of the prime mover.

125. The rotational atherectomy device of claim **124** wherein the coupling shield is biased toward the distal end of the prime mover coupling.

126. The rotational atherectomy device of claim **124** wherein the coupling shield is carried by a base of the prime mover coupling and is biased toward the distal end of the coupling by a compression spring disposed proximally of the shield around the base of the coupling.

127. The rotational atherectomy device of claim **126** wherein the shield presents a generally annular distal face, the distal face of the shield being sized to abut the drive shaft socket, thereby permitting the drive shaft socket to move the shield away from the distal end of the coupling to permit the radially expandable portion of the coupling to be properly received within the socket.

128. The rotational atherectomy device of claim **127** wherein the shield comprises an annular collar which surrounds a length of the radially expandable portion of the coupling.

129. The rotational atherectomy device of claim **128** wherein the base of the prime mover coupling and the collar are fitted together in a tongue-in-groove relationship to guide the collar generally longitudinally along the coupling base and limit rotation of the collar with respect to the base.

130. The rotational atherectomy device of claim **1** wherein the drive shaft carriage further comprises a bearing which supports the drive shaft socket.

131. The rotational atherectomy device of claim **130** wherein the bearing is a ball bearing.

132. The rotational atherectomy device of claim **1** wherein the longitudinally extendable tube includes at least two telescoping tubes.

133. The rotational atherectomy device of claim **132** wherein one of the telescoping tubes is connected to a distal end piece of a housing of the exchangeable drive shaft cartridge while another of the telescoping tubes carries the drive shaft carriage.

134. A rotational atherectomy device comprising:

a) an exchangeable drive shaft cartridge comprising a rotatable drive shaft socket carried by a drive shaft carriage; a catheter; and a rotatable flexible drive shaft having a proximal, intermediate and distal portions, the proximal portion of the drive shaft being attached to the drive shaft socket, the intermediate portion of the drive shaft being disposed primarily within the catheter, and the distal portion of the drive shaft extending distally from the catheter and having an abrasive tissue removal implement;

b) a rotatable prime mover coupling attached to a shaft of a prime mover for rotation therewith, the prime mover coupling including a radially expandable portion;

the drive shaft socket being sized to receive a length of the radially expandable portion of the coupling therein such that the radially expandable portion of the coupling does not contact an interior of the drive shaft socket when the prime mover coupling is not rotating, but the radially expandable portion of the coupling radially expands into frictional engagement with the socket upon sufficiently rapid rotation of the prime mover, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover,

whereby when the prime mover is not rotating, the drive shaft is disconnected from the prime mover, thereby permitting the exchangeable drive shaft cartridge to be replaced by another exchangeable drive shaft cartridge.

135. A rotational atherectomy device comprising:

a) an exchangeable drive shaft cartridge comprising a rotatable drive shaft socket carried by a drive shaft carriage; a longitudinally extendable tube extending distally from the drive shaft carriage; a catheter extending distally from the tube; and a flexible drive shaft having a lumen for receiving a guidewire around which the drive shaft may rotate, the drive shaft having proximal, intermediate and distal portions, the proximal portion being attached to the drive shaft socket, the intermediate portion being disposed primarily within the tube and the catheter, and the distal portion extending distally from the catheter and having an abrasive tissue removal implement;

b) a rotatable prime mover coupling attached to a shaft of a prime mover for rotation therewith, the prime mover coupling including a radially expandable portion;

the drive shaft socket being sized to receive a length of the radially expandable portion of the coupling therein such that the radially expandable portion of the coupling does not contact an interior of the drive shaft socket when the prime mover coupling is not rotating, but the radially expandable portion of the coupling radially expands into frictional engagement with the socket upon sufficiently rapid rotation of the prime mover, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover,

whereby when the prime mover is not rotating, the drive shaft is disconnected from the prime mover, thereby permitting the exchangeable drive shaft cartridge to be replaced by another exchangeable drive shaft cartridge.

136. The rotational atherectomy device of claim **134** or claim **135** wherein the prime mover and the rotatable prime mover coupling are carried by a prime mover carriage, the prime mover carriage and the drive shaft carriage having mating fittings which permit the carriages to be interconnected so they can be moved together as a unit.

137. The rotational atherectomy device of claim **136** wherein the fittings comprise mating components of a bayonet joint.

138. A rotational atherectomy device comprising:

a) an exchangeable drive shaft cartridge comprising a rotatable drive shaft socket carried by a drive shaft carriage; a longitudinally extendable tube extending distally from the drive shaft carriage; a catheter extending distally from the tube; and a rotatable flexible drive shaft having proximal, intermediate and distal portions, the proximal portion being attached to the drive shaft socket, the intermediate portion being disposed primarily within the tube and the catheter, and the distal portion extending distally from the catheter and having an abrasive tissue removal implement;

b) a flexible fluid supply tubing connected to the drive shaft cartridge distally of the drive shaft socket;

c) a rotatable prime mover coupling carried by a prime mover carriage and connected to a prime mover for rotation therewith, the prime mover coupling including a coupling base and at least two flexible pins, each pin being formed of a superelastic material and connected adjacent a proximal end to the coupling base and having a distal end portion which is free to deflect radially outwardly into frictional engagement with an interior surface of the drive shaft socket when the prime mover is rotated;

d) the drive shaft carriage and the prime mover carriage including mating fittings which permit the carriages to be interconnected to move together as a unit;

the drive shaft socket being sized to receive the distal end portions of the pins of the prime mover coupling therein such that the pins do not contact the interior surface of the drive shaft socket when the coupling is not rotating, but the distal end portions of the pins deflect into frictional engagement with the socket upon sufficiently rapid rotation of the prime mover, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover,

whereby when the prime mover is not rotating, the drive shaft is disconnected from the prime mover, thereby permitting the exchangeable drive shaft cartridge to be replaced by another exchangeable drive shaft cartridge.

139. A rotational atherectomy device comprising:

a) an exchangeable drive shaft cartridge comprising a rotatable drive shaft socket carried by a drive shaft carriage; a longitudinally extendable tube extending distally from the drive shaft carriage; a catheter extending distally from the tube; and a rotatable flexible drive shaft having proximal, intermediate and distal portions, the proximal portion being attached to the drive shaft socket, the intermediate portion being disposed primarily within the tube and the catheter, and the distal portion extending distally from the catheter and having an abrasive tissue removal implement;

b) a flexible fluid supply tubing connected to the drive shaft cartridge distally of the drive shaft socket;

c) a rotatable prime mover coupling carried by a prime mover carriage and connected to a prime mover for rotation therewith, the prime mover coupling including a coupling base and at least six flexible pins, each pin being formed of a superelastic material and connected adjacent a proximal end to the coupling base and having a distal end portion which is free to deflect radially outwardly into frictional engagement with an interior surface of the drive shaft socket when the prime mover is rotated;

d) the drive shaft carriage and the prime mover carriage including mating fittings which permit the carriages to be interconnected to move together as a unit;

the drive shaft socket being sized to receive the distal end portions of the pins of the prime mover coupling therein such that the pins do not contact the interior surface of the drive shaft socket when the coupling is not rotating, but the distal end portions of the pins deflect into frictional engagement with the socket upon sufficiently rapid rotation of the prime mover, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover,

whereby when the prime mover is not rotating, the drive shaft is disconnected from the prime mover, thereby permitting the exchangeable drive shaft cartridge to be replaced by another exchangeable drive shaft cartridge.

140. A rotational atherectomy device comprising:

a) an exchangeable drive shaft cartridge comprising a rotatable drive shaft socket carried by a drive shaft carriage; a longitudinally extendable tube extending distally from the drive shaft carriage; a catheter extending distally from the tube; and a rotatable flexible drive shaft having proximal, intermediate and distal portions, the proximal portion being attached to the drive shaft socket, the intermediate portion being disposed primarily within the tube and the catheter, and the distal portion extending distally from the catheter and having an abrasive tissue removal implement;

b) a flexible fluid supply tubing connected to the drive shaft cartridge distally of the drive shaft socket;

c) a rotatable prime mover coupling carried by a prime mover carriage and connected to a prime mover for rotation therewith, the prime mover coupling including a coupling base and at least two flexible pins, each pin being formed of a superelastic material and connected adjacent a proximal end to the coupling base and having a distal end portion which is free to deflect radially outwardly into frictional engagement with an interior surface of the drive shaft socket when the prime mover is rotated;

d) the drive shaft carriage and the prime mover carriage including mating components of a bayonet joint to connect the carriages to one another to permit the carriages to move together as a unit;

the drive shaft socket being sized to receive the distal end portions of the pins of the prime mover coupling therein such that the pins do not contact the interior surface of the drive shaft socket when the coupling is not rotating, but the distal end portions of the pins deflect into frictional engagement with the socket upon sufficiently rapid rotation of the prime mover, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover,

whereby when the prime mover is not rotating, the drive shaft is disconnected from the prime mover, thereby permitting the exchangeable drive shaft cartridge to be replaced by another exchangeable drive shaft cartridge.

141. A rotational atherectomy device comprising:

a) an exchangeable drive shaft cartridge comprising a rotatable drive shaft socket carried by a drive shaft carriage; a longitudinally extendable tube extending distally from the drive shaft carriage; a catheter extending distally from the tube; and a rotatable flexible drive shaft having proximal, intermediate and distal portions, the proximal portion being attached to the drive shaft socket, the intermediate portion being disposed primarily within the tube and the catheter, and the distal portion extending distally from the catheter and having an abrasive tissue removal implement;

b) a flexible fluid supply tubing connected to the drive shaft cartridge distally of the drive shaft socket;

c) a rotatable prime mover coupling carried by a prime mover carriage and connected to a prime mover for rotation therewith, the prime mover coupling including a coupling base and at least six flexible pins, each pin being formed of a superelastic material and connected adjacent a proximal end to the coupling base and having a distal end portion which is free to deflect radially outwardly into frictional engagement with an interior surface of the drive shaft socket when the prime mover is rotated;

d) the drive shaft carriage and the prime mover carriage including mating components of a bayonet joint to connect the carriages to one another to permit the carriages to move together as a unit;

the drive shaft socket being sized to receive the distal end portions of the pins of the prime mover coupling therein such that the pins do not contact the interior surface of the drive shaft socket when the coupling is not rotating, but the distal end portions of the pins deflect into frictional engagement with the socket upon sufficiently rapid rotation of the prime mover, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover,

whereby when the prime mover is not rotating, the drive shaft is disconnected from the prime mover, thereby permitting the exchangeable drive shaft cartridge to be replaced by another exchangeable drive shaft cartridge.

142. The rotational atherectomy device of claim **141** further comprising a flexible fluid supply tubing attached to the exchangeable drive shaft cartridge and in fluid communication with a drive shaft lumen of the drive shaft cartridge, the drive shaft lumen including a reduced inner diameter segment, the reduced inner diameter segment being positioned proximally of where the fluid supply tubing delivers fluid to the drive shaft lumen, thereby reducing flow of fluid proximally along the drive shaft lumen.

143. A rotational atherectomy device comprising:

a) an exchangeable drive shaft cartridge comprising a rotatable drive shaft socket carried by a drive shaft carriage; and a rotatable flexible drive shaft having a proximal, intermediate and distal portions, the proximal portion being attached to the drive shaft socket, the intermediate portion being disposed primarily within a catheter, and the distal portion extending distally from the catheter and having a tissue removal implement;

b) a flexible fluid supply tubing connected to the drive shaft cartridge distally of the drive shaft socket;

c) a rotatable, radially expandable prime mover coupling carried by a prime mover carriage and connected to a prime mover for rotation therewith;

the drive shaft socket being sized to receive a length of the prime mover coupling therein such that the prime mover coupling does not effectively engage an interior of the drive shaft socket when the coupling is not rotating, but the prime mover coupling radially expands to effectively engage the socket upon sufficiently rapid rotation of the prime mover, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover,

whereby when the prime mover is not rotating, the drive shaft is disconnected from the prime mover, thereby permitting the exchangeable drive shaft cartridge to be replaced by another exchangeable drive shaft cartridge.

144. The rotational atherectomy device of claim **143** wherein one of the prime mover carriage and the drive shaft carriage is stationary and the other of the prime mover carriage and the drive shaft carriage can be moved longitudinally with respect to the stationary carriage.

145. A rotational atherectomy device comprising:

a. an exchangeable drive shaft cartridge comprising a housing; a drive shaft carriage positioned proximally of the housing; a rotatable drive shaft socket carried by the drive shaft carriage; a flexible fluid supply tubing connected to the housing distally of the drive shaft socket; a catheter extending distally from the housing; and a rotatable flexible drive shaft having proximal, intermediate and distal portions, the proximal portion being attached to the drive shaft socket, the intermediate portion being disposed primarily within the catheter, and the distal portion extending distally from the catheter and having a tissue removal implement;

b. a rotatable, radially expandable prime mover coupling connected to a prime mover for rotation therewith, the prime mover being carried by a prime mover carriage and the prime mover coupling including a radially expandable portion;

the drive shaft socket being sized to receive a length of the radially expandable portion of the prime mover coupling therein such that the radially expandable portion of the prime mover coupling does not effectively engage an interior of the drive shaft socket when the coupling is not rotating, but the radially expandable portion of the prime mover coupling radially expands to effectively engage the socket upon sufficiently rapid rotation of the prime mover, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover,

whereby when the prime mover is not rotating, the drive shaft is disconnected from the prime mover, thereby permitting the exchangeable drive shaft cartridge to be replaced by another exchangeable drive shaft cartridge.

146. The rotational atherectomy device of claim **134**, claim **135**, claim **143** or claim **145** wherein the prime mover coupling comprises a coupling base and at least two flexible pins, each pin being anchored adjacent a proximal end to the coupling base and having a distal end which is free to deflect radially outwardly to engage the interior of the drive shaft socket when the prime mover is rotated.

147. The rotational atherectomy device of claim **146** further comprising a coupling shield carried by the prime mover coupling, the coupling shield restricting outward deflection of the distal ends of the pins upon rotation of the prime mover when the distal ends of the pins are not properly received within the drive shaft socket.

148. The rotational atherectomy device of claim **138**, claim **139**, claim **140**, claim **141**, claim **143**, or claim **145** further comprising a handle which includes a distal portion adapted to releasably hold the drive shaft cartridge, a proximal portion carrying the prime mover carriage, and an elongated rod connecting the distal and proximal portions of the handle to one another.

149. The rotational atherectomy device of claim **134**, claim **135** or claim **145** further comprising a flexible fluid supply tubing attached to the exchangeable drive shaft cartridge and in fluid communication with a drive shaft lumen of the drive shaft cartridge.

150. The rotational atherectomy device of claim **149** wherein the drive shaft lumen includes a reduced inner diameter segment, the reduced inner diameter segment being positioned proximally of where the fluid supply tubing delivers fluid to the drive shaft lumen, thereby reducing flow of fluid proximally along the drive shaft lumen.

151. A system for releasably connecting a drive shaft to a prime mover comprising:

a) an exchangeable drive shaft cartridge comprising a rotatable drive shaft socket carried by a drive shaft carriage and a rotatable drive shaft having a proximal portion attached to the drive shaft socket;

b) a rotatable, radially expandable prime mover coupling connected to a prime mover for rotation therewith, the prime mover coupling comprising a coupling base and at least two flexible pins, each pin being anchored adjacent one end thereof to the coupling base and having another end which is free to deflect radially outwardly to engage the drive shaft socket when the prime mover is rotated;

the drive shaft socket being sized to receive free end portions of the pins of the prime mover coupling therein such that the pins do not contact the interior surface of the drive shaft socket when the coupling is not rotating, but the free end portions of the pins deflect into frictional engagement with the socket upon sufficiently rapid rotation of the prime mover, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover,

whereby when the prime mover is not rotating, the drive shaft is disconnected from the prime mover, thereby permitting the exchangeable drive shaft cartridge to be replaced by another exchangeable drive shaft cartridge.

152. The system of claim **151** wherein the coupling base includes at least one abutment spaced radially outwardly from each pin when the coupling base is not rotated and limiting outward deflection of an intermediate point along the length of the pin when the prime mover is rotated.

153. A method of removing tissue, comprising:

a) providing a tissue removal device which comprises:

i) an exchangeable drive shaft cartridge comprising a rotatable drive shaft socket carried by a drive shaft carriage; a longitudinally extendable tube extending distally from the drive shaft carriage; an elongated catheter having a proximal end portion which is operatively connected to a distal end portion of the longitudinally extendable tube; and a rotatable flexible drive shaft having proximal, intermediate and distal portions, the proximal portion being attached to the drive shaft socket, the intermediate portion being disposed primarily within the tube and the catheter, and the distal portion extending distally from the catheter and having a tissue removal implement; and

ii) a rotatable, radially expandable prime mover coupling carried by a prime mover carriage and connected to a prime mover for rotation therewith;

b) positioning a length of the prime mover coupling within the drive shaft socket such that the prime mover coupling does not effectively engage an interior surface of the drive shaft socket;

c) rotating the prime mover and the prime mover coupling at a speed sufficient to cause the prime mover coupling to radially expand to effectively engage the socket, causing the socket, the drive shaft and the tissue removal implement to rotate together with the prime mover coupling and the prime mover;

d) contacting tissue with the tissue removal implement;

e) removing tissue with the tissue removal implement; and

f) stopping rotation of the prime mover, thereby disconnecting the drive shaft from the prime mover.

154. The method of claim **153** further comprising, after stopping rotation of the prime mover, replacing the exchangeable drive shaft cartridge with another exchangeable drive shaft cartridge.

155. A method of removing tissue, comprising:

a) providing a tissue removal device which comprises:

i) an exchangeable drive shaft cartridge comprising a rotatable drive shaft socket carried by a drive shaft carriage; a longitudinally extendable tube extending distally from the drive shaft carriage; an elongated catheter having a proximal end portion which is operatively connected to a distal end portion of the longitudinally extendable tube; and a rotatable flexible drive shaft having proximal, intermediate and distal portions, the proximal portion being attached to the drive shaft socket, the intermediate portion being disposed primarily within the tube and the catheter, and the distal portion extending distally from the catheter and having a tissue removal implement; and

ii) a rotatable, radially expandable prime mover coupling carried by a prime mover carriage and connected to a prime mover for rotation therewith;

b) positioning a length of the prime mover coupling within the drive shaft socket such that the prime mover coupling does not effectively engage an interior surface of the drive shaft socket;

c) advancing the flexible drive shaft and the catheter over a guide wire into a body passageway of interest;

d) thereafter, rotating the prime mover coupling at a speed sufficient to cause it to radially expand to effectively engage the socket, causing the socket and the drive shaft to rotate together with the prime mover coupling and the prime mover;

e) advancing the rotating flexible drive shaft and its tissue removal implement against tissue;

f) removing tissue with the tissue removal implement; and

g) stopping rotation of the prime mover, thereby disconnecting the drive shaft from the prime mover.

156. The method of claim **155** further comprising, after stopping rotation of the prime mover, replacing the exchangeable drive shaft cartridge with another exchangeable drive shaft cartridge.

157. The method of **156** further comprising, after replacing the exchangeable drive shaft cartridge, repeating steps b–f.

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